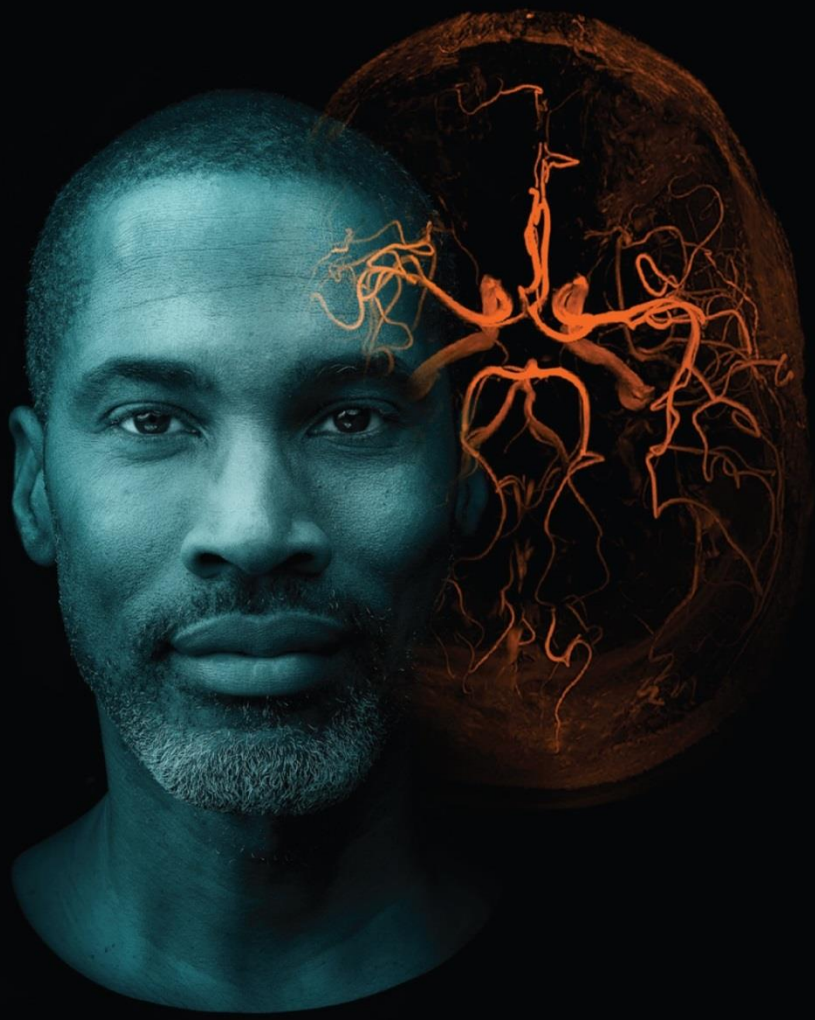
Viva-ProE® System

Operator

Training Workbook



SIEMENS Healthineers

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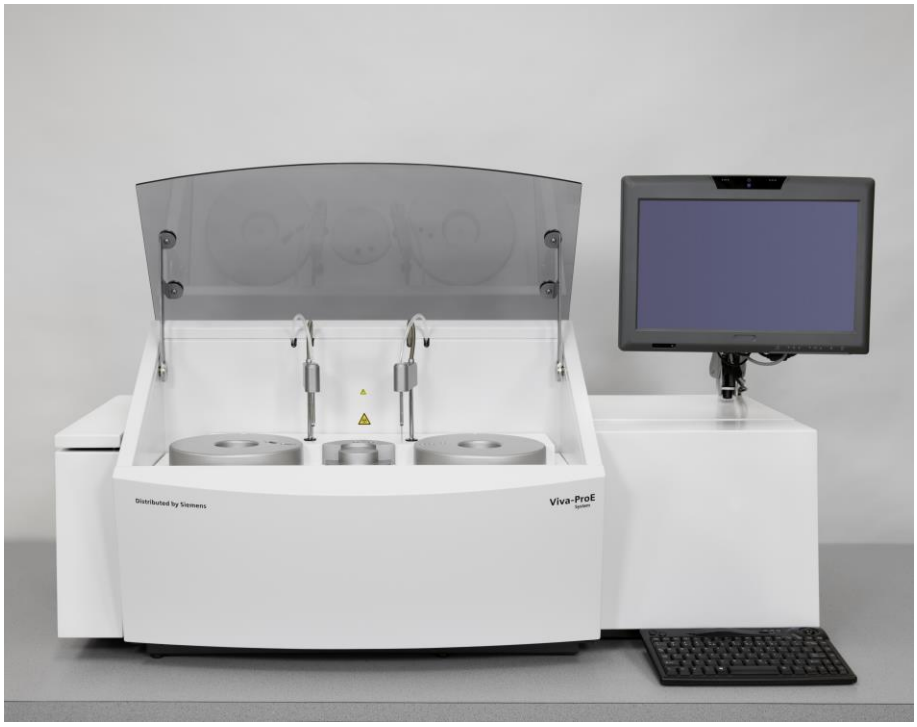
Viva-ProE® System Operator Training Workbook



Siemens Healthineers
Certificate No: UQA 4000486/A

Siemens quality products are manufactured under a quality system that is registered to ISO 13485:2003.

Table of Contents

1 Welcome

Welcome to Training

Siemens Healthineers would like to welcome you to operator training on the Viva-ProE® System.

This course is designed to teach you the skills needed to operate, calibrate, maintain, and troubleshoot the Viva-ProE® System. Our staff welcomes the opportunity to present this training program to you.

Operator Training Course Goals

The goal of this course is to prepare the customer to operate, maintain, and train others on the Viva-ProE System.

Course Objectives

After participating in classroom lectures and exercises, you will be able to:

- Operate the Viva-ProE System, from requesting samples to viewing results.
- Identify components of the Viva-ProE System.
- Navigate the system software.
- Use the instrument's onboard *Operator's Guide.*
- Perform maintenance procedures.
- Request and process calibration, controls and samples.
- Evaluate calibrations, controls and sample results.
- Define the EMIT® principle.
- Identify and resolve basic system errors.

Training Agenda

Morning		Afternoon
Day 1 System Overview • Component Identification exercise Good Laboratory Practice (presentation) Using QRG: • Perform Start of Day • Process controls Review	Lunch	Principles of Calibration and Controls (presentation) Hands-On Exercises: • Process and Evaluate Calibration and Controls • Process and evaluate sample results • Perform End-of-Day Tasks Review
Day 2 EMIT Principle (presentation) Perform Start of Day / Controls /Samples Syva Validity Tests (presentation) • Discuss processing and evaluating Creatinine Calibration and Controls Hands-On Exercises: • Process Creatinine Calibration and Controls • Process Samples Review	Lunch	Using QRG perform: Instrument Maintenance • Weekly • Monthly • Quarterly • Semi-annual • As Needed Perform a System Database Backup Discuss using the *Operator's Manual*
Day 3 Hands – On Exercises: • Reagents Perform Troubleshooting • Perform Start of Day • Run QC for "All Tests" • Run sample for "THC and Creatinine only Review	Lunch	Navigate System Additional Software Screens Hands-On Exercise: • Calibrate and run controls on "All Tests" Discuss Instruction for Use (IFU) Wrap-up Forms

Course Validation Checklist

The student places a checkmark beside the competency when it is completed. When all competencies are checked, the instructor and operator sign and date below as a record of completion.

Topics	Competencies	Completed
System Overview	Identify the system hardware components	
	Identify system hardware functions	
	Describe the function of the software icons	
Start of Day	Access the Start of Day checklist	
	Perform the tasks on the Start of Day checklist	
Daily Controls	Request and process controls for Drugs of Abuse (DAT)	
	Evaluate control results	
Samples	Navigate software to request samples and assign to the sample rotor	
	Pipette / pour samples into tubes	
	Load and process samples	
Calibration and Controls (DAT)	Navigate software to request calibration and controls and assign to the sample rotor	
	Pipette / pour calibrators and controls into cups and place on top of pediatric adaptors	
	Load and process calibrators	
	Evaluate calibrations to accept or reject results	
	Evaluate control results and separations	
	Describe the QC screen	
End of Day	Access the End of Day checklist	
	Perform the End of Day checklist	

Day 2 -Daily Startup/ Daily Controls / Sample Processing	Perform the daily startup tasks; Request, process and evaluate daily controls; Request and process samples.	
EMIT® Principle	Describe the technology of the EMIT®	
Syva Validity Tests	Instructor Led: Add creatinine to the test menu.	
	Request, process and evaluate creatinine calibration and controls	
	Request, process and evaluate samples	
	Rerun positive samples	
	Perform End of Day tasks	
Maintenance	Perform Weekly needle rinse of probes	
	Describe Monthly cleaning of water and waste containers; Describe filling the cooling reservoir; Perform cleaning the reagent rotor compartment	
	Perform Quarterly changing the drying block.	
	Perform Semi-annual replacing the stirrer belt; describe changing the water filter; describe the clean system	
	Perform As Needed changing the cuvette rotor	
System Backup	Perform a system database backup	
	Transfer database and archive backup files to an external media device	
Day 3- Troubleshooting	Reagent Info Screen	
	Resolve troubleshooting scenarios	
Navigating the Software	Instructor Led: Navigating additional software screens	
Resources	Discuss the Instructions for Use (IFU)	
	Using the Viva-ProE Operator's Manual	

Instructor: _____

Participant: _____

Date: _____

What was most helpful to you during this program?

_____

_____

_____

How can we improve this program to make it more meaningful to you?

_____

_____

_____

Training Center Safety Information

While you are at the training center, please follow these safety practices:

- In the event of a fire alarm, a loud noise will sound continuously and the lighted fire sign will blink. Stop work immediately and leave the building through the nearest exit. Follow an instructor to the meeting area in the front of the building.
- Note the position of the fire extinguisher.
- Use the eyewash located near the sink if you should happen to get anything in your eye(s).
- Report any injury to an instructor.
- No eating, drinking, storing food, or applying cosmetics in the classroom.
- Safety glasses must be worn when you are working on the instrument. In biohazard classrooms, blue lab coats must also be worn. Do not wear these garments outside the classroom or when you are sitting at the classroom tables.
- Dispose of waste materials appropriately:
    - Paper Waste: Use standard containers with clear plastic liners for all paper products.
    - Biohazard Waste: Use waste containers with red plastic liners for contaminated sample cups, tubes, reagents and controls.
- Wash your hands before leaving the classroom or after removing gloves.

2 System Overview

System Overview

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Identify the system hardware components.
- Identify the system hardware functions.
- Describe the function of the software icons.

Identify System Hardware Components

Identify the location of each of the components. Record the number in the photo next to the name of each component below:

_____ Panel PC/Touchscreen

_____ Sample Probe

_____ Reagent Rotor

_____ Sample Rotor

_____ Cabinet for Treated Water and Diluted Waste

_____ Cuvette Rotor

_____ Cabinet for Pipettors

_____ Cabinet for Concentrated Waste

_____ Reagent Probe

Identify System Hardware Functions

1. Open the safety cover on the instrument and answer the following questions.
   a. Where does the measurement occur after the addition of the sample and reagents?

   b. Where are the large reagent bottles placed on the Reagent Rotor?

   c. How many samples can be placed in the Sample Rotor?

   d. Where is the internal barcode reader located?

2. Locate the reservoir that holds the cooling fluid.
   a. Where is this located?

   b. What is the purpose of the cooling fluid?

3. Close the safety cover. Locate the Reagent and Sample Pipettors.
   a. What is the size of the syringe that is used for Reagents?

   b. What is the size of the syringe that is used for Samples?

4. Open the cabinet under the Panel PC and keyboard.
   a. What is added to the distilled or deionized water in the Treated Water container?

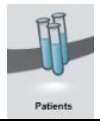
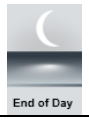
   b. How much?

5. Open the cabinet on the left side of the Viva-ProE System.

   Where does the waste come from that is inside the Diluted and Concentrated Waste container?

Describe the Function of the Software Icons

Use the Viva-ProE System software to match the icon on the left with the proper function listed on the right.

1. Start of Day _____ 	a. Request, load and run calibrators. View the status of calibrators currently requested on the system and the status of samples in the Sample Rotor.
2. Reagents _____ 	b. Used to start the run (if the system is idle) or Pause the run (if the system is running).
3. Calibration _____ 	c. Display a list of tasks that must be performed at the start of each day.
4. Control _____ 	d. View patient sample, calibration and control results. Also search for patient results and accept or reject calibrations (with the proper software access).
5. Process / Pause _____ 	e. Display a list of tasks that must be performed at the end of each day.
6. Patients _____ 	f. Review status of samples in the Sample Rotor and remove samples that are complete.
7. Results _____ 	g. Request, load and run controls. View the status of controls currently requested on the system and the status of samples in the Sample Rotor.
8. Unload _____ 	h. View the status of the Reagent Rotor and load, unload, replace and extend reagents.
9. End of Day _____ 	i. Request samples and enter patient information. Assign samples to locations on the Sample Rotor.

6. Select the QC icon from the Home screen.
   a. What information is available from this screen?

7. Return to the Home screen
   a. Which icon will stop the system if it is selected?

   b. Which icon provides information about the status of the system, such as unavailable tests?

   c. Which icon can be selected to view the Operator's Guide?

3 Start of Day

Start of Day

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Access the Start of Day checklist.
- Perform the tasks on the Start of Day checklist.
- Update new lot numbers and expiration dates of solutions in software.

Access the Start of Day Checklist

1. Which icon on the Home screen is used to access the Start of Day checklist?

2. Access the checklist.

Perform the Tasks on the Start of Day Checklist

1. Use the Viva-ProE System *Quick Reference Guide* or the *Operator's Manual* to perform the tasks on the Start of Day checklist.
   a. What is available in the software that can provide assistance with any of the screens?

   b. What is the purpose of adding the System Solution to prepare the Treated Water?

   c. When priming the system, which instrument components need to be checked for bubbles and/or air gaps?

   d. What indicates the cuvette blank is acceptable?

   e. What information is provided on the Daily Report?

   f. What is used to refill the 10% Cleaning Solution (also the Probe Rinse)? What is this solution used for?

      Perform this task: The 10% cleaning solution (Probe rinse) has expired. The new lot number is 401007 and the expiration date is 12/31/20xx (where xx is the current year). Replace the 10% cleaning solution in the software.

g. Which position on the Sample Rotor holds the 10% Cleaning Solution / Probe Rinse?

h. How can the volume of the reagents and the Acid Solution be checked without looking inside the bottles?

i. What is the purpose of the 0.1N HCl Acid Solution?

Perform this task: The 0.1N HCl Cleaning Solution (Acid Solution) has expired. The new lot number is 45181 and the expiration date is 12/31/20xx (where xx is the current year). Replace the cleaning solution in the software.

j. How long are the reagent bottles good once they are on board the system?

k. How will the system let you know when the bottles have expired?

2. What else is required to be performed daily prior to processing samples that ensures the accuracy of the test results?

4 Daily Controls

Daily Controls

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Request and process controls for Drugs of Abuse (DAT).
- Evaluate control results.
- Unload completed samples.

Request and Process Controls

Scenario: After performing the Start of Day activities, controls must be run prior to processing samples to ensure the accuracy of the results. Use the QRG or *Operator's Guide* to run the following controls:

Level 0 (used for the negative control)

Level 5 (used for the positive control)

Level 4 (6-AM) is the positive control for the 6-Acetylmorphine test

Label the cups 0, 5 and 4 (6-AM).

1. What is seen on the Home screen (daily) that indicates controls require processing?

2. What is the indicator that a control has been assigned to the sample rotor?

3. Why is it important to run QC daily?

Evaluate Control Results

1. View the control results for all tests that were processed.

   How do you view control results?

2. How do you know if the controls passed?

3. Select a test. What other information is available on the screen?

4. Does the system allow tests to be run if the control has failed for those tests?

Unload Completed Samples

Remove the completed samples from the sample rotor in the software.

1. Which icon allows you to unload samples from the sample rotor?

2. What are the 2 choices you have for removing samples from the sample rotor?

5 Calibration and Controls

Calibration and Control - DAT

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Request and process qualitative calibrations.
- Evaluate calibration results.
- Evaluate control results.
- Describe the QC screen.

Request and Process Qualitative Calibrations

Scenario: Your facility or lab has decided to calibrate weekly as recommended. Today is the scheduled day to calibrate. Controls must also be processed and evaluated for accuracy prior to processing samples.

Using the Quick Reference Guide, perform the following actions:

- Print out the previously stored calibrations.
- Request and process calibrations for all tests.
- Process controls Level 0, Level 5 and Level 4 (6-AM).
- Evaluate calibration results.
- Evaluate control results.
- View QC table and graph.

While the calibrations and controls are running:

- Answer the questions in this exercise
- Program the samples found in Section 6

1. Which calibrator level was used to calibrate the following tests?
    a. Amphetamines (AM5)
    b. Cocaine (C15)
    c. Opiates (OP3)
    d. Cannabinoids (T50)
    e. 6-Acetylmorphine (6-AM)
2. What does the number mean after the test name (e.g. C15)?

3. What drug does 6-AM test for?

Evaluate Calibration Results

1. If the system is still active, what is the indicator that will tell you when calibrations and controls are done testing?

2. What needs to be done with the calibration results?

3. Describe how to evaluate calibration results.

4. View the calibration results for all the tests.
   a. What is the previous and current calibration rate?

	Previous	Current	Accepted?
AM5			
C15			
T50			
OP3			
6-AM			

5. What else is used to validate the calibration results?

6. Identify and discuss any calibration issues.

Evaluate Control Results

1. What are the results of the tests processed for Level 0?

2. What are the results of the tests processed for Level 5?

3. What are the results for Level 4 (6-AM)?

4. Evaluate all tests for control acceptance. Identify and discuss any control issues.

Describe the QC Screen

Select the QC icon to view results.

1. Select the Controls radio button. What is displayed?

2. Select the Tests radio button. What is displayed

3. Select the white triangle before Cocaine 150 and select Level 0. What is displayed?

4. What is the Expected Separation for Level 0, Cocaine 150?

5. What do the points on the graph represent? Are they good or bad – why or why not?

6. Select the white triangle in front of THC50. Select Level 5 (Positive). Select the Table tab at the top of the screen.
   a. Describe what is displayed.

   b. Are these values from the same points on the graph?

6 Sample Processing

Sample Processing

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Create and process samples.
- Evaluate sample results.
- Unload completed samples.

Create and Process Samples

Scenario: Judge Judy has requested sample testing and evaluation of results for several clients.

1. Create and process the following samples.

Sample ID	Name	Test
1234	Nancy Jones	T50, OP3
1235	Jack Philips	AM5, C15
1236	Mary Meyers	Panel – ALL TESTS
1237	KO Kane	Panel – ALL TESTS
1238	Sam Sha	Panel – ALL TESTS

2. Which icon is selected to create samples?

3. What is selected to assign samples to a position on the sample rotor?

4. Assign sample positions. What color are the assigned samples on the rotor?

5. After selecting process, what indicates that the samples are processing?

6. How do you know when samples are completed?

Evaluate Sample Results

1. From the Results screen, select 1234 Nancy Jones that was just tested.

   What are the results?

2. What indicate results have been automatically accepted?

3. Print the results for that sample.

Unload Completed Samples

Remove the completed samples from the sample rotor and software.

Note: Because this is a training class, samples will be poured back into their original containers to be reused.

Perform End of Day

Use the Quick Reference Guide to perform the end of day .

1. Why is it necessary to check / empty the waste?

2. Why is it necessary to check / refill treated water container?

7 Start of Day / Daily Controls / Sample Processing

Start of Day / Daily Controls / Sample Processing

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Perform the Start of Day
- Process Daily Controls
- Process Samples
- Process a STAT sample

Perform Start of Day

1. What indicates the Start of Day tasks need to be performed?

   Perform the Start of Day using the Quick Reference Guide.

2. Select the Info icon  on the Home screen. What does it say?

3. Can the controls be programmed and loaded onto the sample rotor as the system is priming?

Process Daily Controls

Process controls using the Quick Reference Guide.

4. Why are controls run daily?

5. Can samples be programmed as controls are processing?

6. When can the samples be loaded or assigned a sample position?

7. Can the samples be processed when loaded onto the sample rotor? Why or why not?

Process Samples

Scenario: Drug Court is now in session. Four urine samples need to be tested and results need to go to the judge ASAP.

Using the Quick Reference Guide, program and process the following samples.

Sample ID	Name	Test
1237	Ko Kane	T50, OP3
1238	Sam Sha	AM5, C15
???? (Create ID #)	Eva Syva	Panel – ALL TESTS
9004	B. Drug Free	Panel – ALL TESTS

The samples are in process and a new sample has arrived. The judge needs these results immediately.

Program and process the following sample. Select request type STAT.

Sample ID	Name	Test
9001	Jerry Seinfeld	AM5, T50

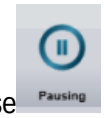
8. Can the STAT sample get loaded on the system when it is processing?

9. What can happen if the glass cover is lifted when the system is processing and the system is not paused first?

Procedure to load and process a STAT sample:

- Select the STAT icon 

at the bottom of the screen or select the Patients icon, enter the sample ID, select Create and select the Stat button. Type in the name, select the tests and Accept.
- Wait for the sample loadable to appear 

before lifting the glass or select pause and wait for pause 

to appear. A chime will be heard.
- Select Load on the Patients screen to assign the STAT sample to a position on the rotor.
- Load the sample into its assigned position on the sample rotor.
- Close the glass lid and select the resume icon 

10. Select the Home screen icon and the Info icon. What do you see?

11. Review the test results for Jerry Seinfeld. What indicates a sample result requires the operator to review? What needs to be done with this result?

8 Calibration and Control - Validity

Calibration and Control - Validity

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Request and process quantitative calibration and controls
- Evaluate Calibration results.
- Evaluate Control results.
- Describe the QC Screen.

Request and Process Quantitative Calibration and Controls

Scenario: Your facility has decided to increase the effectiveness of its drug testing program by adding Creatinine to the test menu. Prior to running samples, calibration and controls must be performed and evaluated for accuracy.

Using the Quick Reference Guide, perform the following actions:

- Request and process calibration.
- Process UTAK controls Validity 3 and Validity 4.
- Evaluate calibration and control results.
- View QC table and graph.

While the calibration and controls are processing:

- Answer the questions in this exercise
- Program the samples found in Section 9
- Process samples after calibration and controls are completed and valid.

Evaluate Calibration Results

List your calibrator Rates for Creatinine in the following chart

Calibrator	Previous	Current	Accepted?
2.0 mg/dL			
20.0 mg/dL			

1. What is the indicator that will tell you when calibrations and controls are done testing?

2. What needs to be done with the calibration results?

3. Describe how to evaluate calibration results.

4. Identify and discuss any calibration issues (Bonus learning opportunity).

Evaluate Control results

List your control ranges and results in the following chart

Controls	Range	Results
Validity 3		
Validity 4		

5. Are your controls acceptable?

6. If the controls are out of range, can samples be processed for this test?

7. Identify and discuss any calibration issues (Bonus learning opportunity).

Creatinine Calibration Troubleshooting Example

Calibrator	Previous Rate	Current Rate
2.0 mg/dL	0.004	0.004
20.0 mg/dL	0.045	0.035

Is this a Good Calibration?

No. This is what may be noticed if the Creatinine R1 reagent loses its stability.

If the calibration is accepted the QC may be in range. However your results may be compromised.

Remember: The calibration rate should be very close to the previous rate.

Note: Creatinine Calibrators are stable for 21 Days per the IFU.

Describe the QC Screen

Select the QC icon to view results.

1. Select the tests radio button. Select the white arrow before Creatinine and select UTAK Validity 3. What is displayed?

See below: This is seen above the table and graph. Where do the Target, Low and High numbers come from?

UTAK Validity 3 - Creatinine									
QC Rules:	Basic	Average	3.35	SD	0.14	CV	4.2 %	N	35
Unit:	mg/dL	Target:	3.50	Low	3.00	High	4.00		

2. Select the Graph tab. Select a point on the graph.
   a. What are the date, time and value for the selected point? (displayed at bottom of the screen)

   b. Select arrow to display next point.

3. What symbol indicates a value (point) is outside of the control range?

4. Select the Table tab.
   a. Select a date and select exclude. What happens?

   b. Why would a result need to be excluded?

9 Sample Processing - Validity

Sample Processing - Validity

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Create and process samples.
- Pause system to add a sample.
- Rerun positive samples.
- Evaluate results.
- Perform End of Day tasks.

Create and Process Samples

Scenario: A probation officer suspects their clients have been drinking large amounts of water to mask THC results. The Creatinine test will be processed with all samples to determine sample validity.

Program and process the following samples:

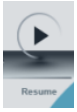
Sample ID	Name	Test
1235	Jack Phillips	T50, CR
1236	Mary Myers	T50, CR
9001	Jerry Seinfeld	Panel – ALL TESTS
9004	B. Drug Free	Panel – ALL TESTS

Note: After the above samples have begun processing, Dee Tox sample needs to be added.

9006	Dee Tox	Panel – ALL TESTS

- In the Patients screen, program Dee Tox sample.
- In the Load Patients screen, select Load. Does the system assign a position for this sample?
- Select the pause icon. 

What does the icon change to?
- Wait for the system to "chime" and the processing icon will show sample loadable. 

In what other location is the checkered flag with sample tubes seen?
- Assign a position to the sample in the Load screen. Lift the glass lid and place the sample in its assigned position. Close the glass lid and select the resume 

icon.

1. How much time to results _____ sample loadable _____ loadable _____ Standby_____
2. Define sample loadable, loadable and standby.

Rerun Positive Samples

For all samples that have positive test results, pour a fresh sample from the collection cup. From the Patients screen, enter the Sample ID and add “rerun” to the ID. Select Create, select the test(s) to run, select Load and select Resume.

3. Why do you pour a fresh sample when rerunning positive samples?

Evaluate Results

4. (Circle the correct response below) Creatinine results less than 2 mg/dL indicates the samples may be:

   Substituted Diluted

5. Circle the correct response below) Creatinine results less than 20 mg/dL indicates the samples may be:

   Substituted Diluted

Perform End of Day Procedures

6. Why is the Viva-ProE system not shut off at the end of day?

10 Maintenance

Maintenance

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Perform weekly maintenance.
- Discuss monthly maintenance.
- Perform quarterly maintenance.
- Perform and discuss semi-annual maintenance.
- Perform and discuss as-needed maintenance.

Perform Weekly Maintenance

Perform the probe rinse procedure.

1. Which icon from the Home screen is used to access the maintenance tasks, including performing the probe rinse?

2. What solution is used to rinse the probes? In what locations does the solution go on the system?

Discuss Monthly Maintenance

1. What solution is used to clean the treated water and waste containers?

2. What is required to be done on the system after this maintenance is performed?

Perform the 'Filling the Cooling Fluid' activity (if needed).

3. When does the cooling fluid reservoir require filling?

4. Fill in the blanks: ____ part cooling fluid is diluted with _____ parts distilled water.

Perform clean reagent rotor compartment.

5. What needs to be done prior to removing the reagent rotor?

Perform Quarterly Maintenance

Remove the drying block and replace using the same one.

1. What happens when 'Replace Drying Block' is selected on the right side of the screen?

2. When removing the screw over the dryer block, what type of screw driver is used?

3. When tightening the screw, where is the dryer block located?

Perform and Discuss Semi-annual Maintenance

Remove the stirrer belt and replace with the same one.

1. What needs to be done to return the system to a stand-by state?

2. Describe how to replace the water filter. (Do not perform this maintenance)

3. Does the system require resetting after performing this activity?

Review the process for cleaning the system. (Do not perform this maintenance)

4. How much sodium hypochlorite cleaning solution is used during this process?

5. Approximately how long will “Clean the System” take?

Perform and Discuss As-needed Maintenance

Replace the cuvette rotor using the same rotor that is in the system.

1. When does the cuvette rotor get changed?

2. How many tests were performed on the cuvette rotor? (Hint: Cuvette Rotor Usage Count)

3. What is required to be performed on the new cuvette prior to testing?

Month/Year: .....

Daily maintenance	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**
Empty waste containers (par. 5.2.2).																															
Fill treated water container (par. 5.2.2).																															
Prime the system and check syringes (par. 5.2.2).																															
Check cuvette blank (par. 5.2.3).																															
Check/Replace 10% cleaning solution in W position of sample rotor (par. 5.2.2).																															
Check daily report (par. 5.2.2).																															
Check reagent rotor compartment (par. 7.2.6).																															
Check acid solution on reagent rotor (par. 5.2.4).																															
Check reagent inventory (par. 5.2.4).																															
Initials																															

Month/Year: .....

Weekly maintenance	Week 1	Week 2	Week 3	Week 4	Week 5
Rinse probes (par. 7.2.2).					
Initials and Date					

Year: .....

Montly maintenance	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Clean treated water and waste containers (par. 7.2.3).												
Check/fill cooling fluid (par. 7.2.4).												
Clean exterior of the instrument (par. 7.2.5)												
Clean reagent rotor compartment (par. 7.2.6)												
Initials and Date												

Quarterly maintenance	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Replace drying block (par. 7.2.7).				
Initials and Date				

Semi-annual maintenance	Half year 1	Half year 2
Replace stirrer belts (par. 7.2.8).		
Replace water filter (par. 7.2.9).		
Run the clean system procedure (par. 7.2.10)		
Initials and Date		

Yearly maintenance	
Replace syringes (par. 7.2.11).	
Replace photometer lamp (par. 7.2.12).	
Initials and Date	

Every 10,000 tests maintenance						
Replace cuvette rotor (par. 7.2.14).						
Initials and Date						

11 System Backup

System Backup

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Perform a system database backup.
- Transfer database and archive backup files to an external media device.

Transfer Database and Archive Backup Files to an External Media Device

1. When does the system automatically perform a system backup?

2. How many backups does the system retain?

3. What type of data or information is stored in the backup files? (Find this in the *Operator's Guide* on-board)

4. How can you tell which backup file is the latest one?

5. Where are archive files stored?

6. What is the purpose of archiving the database?

7. How are archived patient results retrieved? Search Nancy Jones test result(s) ID# 1234.

8. Why is it important to place a copy of the database and archive backup files to an external device?

12 Reagents

Reagents

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Access and describe the Reagents Info screen.
- Identify reagent positions and correctly place reagents on the rotor
- Replace reagents in the software

Access the Reagents screen

Scenario: It is a new day. Reagent bottles placed on board the system are good for 28 days. The bottles on board have expired and were discarded. New bottles have been labeled, filled with reagent and need to be placed on the system.

Access the appropriate screen and load the reagents according to the assigned reagent position.

1. Which screen is selected to load the reagent bottles?

2. Does the system alert you if the bottles are loaded incorrectly?

3. What happens if the bottles are loaded incorrectly?

4. Is it necessary to calibrate any of these reagents?

5. On the Reagent Info screen, how many tests are available to process T50 on the system?

6. Is the current number of tests listed for T50 correct?

7. How does the system update the test count for each assay?

Perform the Start of Day

Process Daily Controls

Process three samples and select any tests.

13 Troubleshooting

Troubleshooting

Resources

- *Operator's Guide (available from the Help icon)*
- *Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to:

- Address various troubleshooting scenarios.
- Resolve System error messages.
- Identify System inactive status.
- Restore System to standby status.
- Resolve Calibration issues.
- Resolve QC failures.

Scenario: It is a new day.

Instructions: Perform Start of Day

1. List any issues found while performing this task.

2. What is the status icon and where is it located?

3. How did this issue(s) get resolved?

4. What is required to be done if the cuvette blank fails due to a bad cuvette or cuvettes?

5. Describe any other issues that may have occurred.

Scenario: The daily startup is completed and samples are waiting to be processed.

Instructions: Run QC for “All Tests”

1. List any issues found while performing this task.

2. What is the status icon and where is it located?

3. How did this issue(s) get resolved?

4. When is this issue likely to occur in your lab or facility?

5. Describe any other issues that may have occurred.

Scenario: Your facility is testing samples for THC and Creatinine only today.

Instructions: Run samples for "THC and Creatinine".

1. List any issues found while performing this task.

2. What is the status icon and where is it located?

3. How did this issue(s) get resolved?

4. When is this issue likely to occur in your lab or facility?

5. Describe any other issues that may have occurred.

Scenario: Your Field service engineer performed a PM (Preventative Maintenance) on your analyzer today. To ensure your analyzer is operating properly you calibrate and run controls on all tests.

Note: New lot calibrator level 1 is G3, Expires 12-31-20xx (xx is current year)

Instructions: Calibrate and run controls on all tests.

1. List any issues found while performing this task.

2. What is the status icon and where is it located?

3. How did this issue(s) get resolved?

4. When is this issue likely to occur in your lab or facility?

5. Describe any other issues that may have occurred.

14 Instructions for Use

VALIDITY CONTROLS 1 – 5

ADULTERANT TOXICOLOGY CONTROL

I. INTENDED USE:

The UTAK Validity Controls 1 – 5 are for use as quality control materials that will help identify substituted, diluted, and adulterated urine samples. The control material will generate data that checks and evaluates a test method. In the case of screening, it is important to have a control material that contains the desired analyte at or near the desired cut off value so that a continuous quality control program is obtained.

II. SUMMARY AND PRINCIPLES:

Several different techniques are used for evaluating or estimating the variance of results. The three subjects summarized below must be considered with any test method.

1. PREVENTIVE MEASURES:
   These measures are usually contained in the design of the test method and include consideration for reagents, equipment, and operator errors. These measures are designed to minimize variance.
2. QUALITY CONTROL MEASURES:
   When a quality control sample is analyzed at the same time and in the same manner as a patient specimen, an estimate of variance is obtained for the test method. This estimate of variance can be compared to the acceptable limits of variance of the test method.
3. STATISTICAL ANALYSIS OF PATIENT RESULTS:
   As an aid in evaluating overall test results, the past experience of expected results can be compared to the results of any given test run. For example, it would not be expected that all results of a given test run be in an elevated range.

Quality control materials are widely used as a means to aid in the evaluation of test results. The following subjects are to be considered in the use of any control material.

1. Multi-Level	LOW / NORMAL / ELEVATED
2. Matrix	HUMAN / ANIMAL / CHEMICAL
3. Availability	SUFFICIENT FOR STATISTICS
4. Form	LIQUID / FROZEN / DRIED
5. Variety	DIFFERENT THAN CALIBRATORS

The UTAK Validity Controls 1 – 5 will generate data that check and evaluate the results of a test method over the low, normal, and elevated ranges. The principles of statistics require that the same material be available for comparison for any given time period. Statistical accuracy requires that a test method be defined for variance and be calibrated with a suitable standard. The quality control materials that are used must be of a sufficient variety so that the measurements and the data that are obtained are independent of the calibration standards. By using a variety of materials, the entire test method can be continuously evaluated to insure reliable results.

III. PRODUCT DESCRIPTION:

The matrices for UTAK Validity Controls 1 – 5 are prepared from distilled water. The levels of the Adulterants, Creatinine, Specific Gravity, and pH are adjusted to the desired range for each lot prepared. Quality control before, during, and after the preparation of the control material insures that each lot is comparable and of the same high quality. The listed ranges were verified by analytical methods similar to those actually used in a testing laboratory.

IV. PRECAUTIONS:

1. For in vitro diagnostic use only.
2. For analytical use only.

V. STORAGE AND STABILITY:

1. Store liquid control material at 2-8°C (35-46°F).

VI. PROCEDURE:

1. Swirl gently 3-4 minutes to insure a homogeneous mixture.
2. Swirl gently each time an aliquot is removed to ensure a homogeneous mixture.
3. Assay control material in the same manner as patient specimens, following the exact same instructions from the entire test method.
4. Record the results obtained on a quality control chart that describes statistical limits for the test method(s) and the specific lot of quality control material.

VII. LIMITATIONS:

1. Control material is for use in quality control programs only; it is not intended for use as a calibration standard.
2. Check the lot number on each vial to be sure it corresponds to the lot number printed on the insert.
3. Laboratories should establish their own values for mean and expected ranges.
4. Results are dependent upon proper storage and adequate mixing.
5. Control material approximates a patient specimen; it has not been assayed for any analytes not listed in the table below.

VIII. EXPECTED VALUES:

1. Listed in the table below are the Target Ranges; each Target Range is verified by analysis performed by independent laboratory testing.
2. The mean of several determinations may not duplicate the quantitative values listed below, but should fall within an acceptable range for the specific analytical test method used.

VALIDITY CONTROLS 1 – 5

Expiration Date: 10/11	Level 1 Product # 17010	Level 2 Product # 17011	Level 3 Product # 17012	Level 4 Product # 17013	Level 5 Product # 17014
	Lot #: 3844	Lot #: 3845	Lot #: 3846	Lot #: 3847	Lot #: 3848
	Target Range	Target Range	Target Range	Target Range	Target Range
Chromium VI (µg/mL)	n/a	0	n/a	n/a	>65
Creatinine (mg/dL)	n/a	1.0 - 1.5	3.0 - 4.0	21 - 25	n/a
Nitrites (µg/mL)	500 - 625	0	200 - 250	n/a	n/a
Oxidants (µg/mL)	n/a	0	n/a	n/a	>65
pH	4.5 - 9.0	3.2 - 4.0	10.0 - 10.8	2.0 - 2.8	11.2 - 12.0
Specific Gravity	1.0020	1.0210 - 1.0250	0.9950 - 1.0005	1.0040 - 1.0180	n/a

For technical assistance call: UTAK Technical Service (800) 235-3442

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PRODUCT NUMBER:
17010-14
1x25ML VIALS, LIQUID

EC AUTHORIZED REPRESENTATIVE
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Rev. 10/09

SIEMENS

Syva®

Emit® II *Plus* Amphetamines Assay

See shaded sections:
Updated information from 2018-03 version.

10871338_H

Amphetamines Assay

1 Intended Use

The Emit® II Plus Amphetamines Assay is a homogeneous enzyme immunoassay with a 300 ng/mL, 500 ng/mL (SAMHSA initial test cutoff level) or 1000 ng/mL cutoff.[1] The assay is intended for use in the qualitative and semiquantitative analyses of amphetamines in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Amphetamines Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.[2] Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

2 Summary and Explanation of the Test

Amphetamines are central nervous system stimulants that produce wakefulness, alertness, increased energy, reduced hunger, and an overall feeling of well being. The term "amphetamines" refers to a group of drugs that includes d-amphetamine, d-methamphetamine (*N*-methyl derivative of amphetamine), d,l-amphetamine, methylenedioxyamphetamine (MDA) and methylenedioxymethamphetamine (MDMA).[3] Amphetamines can be inhaled, taken orally, intravenously, or by smoking.[3]

Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine. The relative importance of these elimination modes depends on urinary pH. Amphetamine is metabolized to deaminated (hippuric and benzoic acids) and hydroxylated metabolites. Methamphetamine is partially metabolized to amphetamine, its major active metabolite.[3]

Amphetamines appear in urine within three hours after any type of administration[4] and can be detected by this Emit® assay for as long as 24–48 hours after the last dose.[2] The Emit® II Plus Amphetamines Assay detects both d-amphetamine and d-methamphetamine. The assay also detects d,l amphetamine, d,l methamphetamine, l-amphetamine, l-methamphetamine, methylenedioxyamphetamine (MDA), methylenedioxymethamphetamine (MDMA) and methylenedioxyethylamphetamine (MDEA) in human urine (see Table 14). The assay contains monoclonal antibodies and is therefore less subject to interferences from amphetamine-like compounds than assays containing polyclonal antibodies. While interferences are reduced with this assay, like any immunological test, some interfering compounds do exist. For this reason, confirmation of preliminary positive results is always recommended.

Methods historically used for detecting amphetamines in biological fluids include liquid chromatography, gas-liquid chromatography, fluorometry, and enzyme immunoassay.[5]

While confirmation techniques other than GC/MS may be adequate for some drugs of abuse, GC/MS is generally accepted as a vigorous confirmation technique for all drugs, since it provides the best level of confidence in the result.[2]

3 Principle

The Emit® II Plus Amphetamines Assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in human urine.[6] The assay is based on competition between drug in the specimen and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity. Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme NAD functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

4 Reagents

REF	Product Description	Volume
9C039UL/ 9C309UL/ 9C329UL	**Emit® II Plus Amphetamines Assay Antibody/Substrate Reagent 1** Mouse monoclonal antibodies to d-amphetamine (61 µg/mL) and d-methaphetamine (10 µg/mL),* bovine serum albumin, G6P (5.5 mM), NAD (3.5 mM), preservatives, and stabilizers	29 mL/ 115 mL/ 1000 mL
	Enzyme Reagent 2 Amphetamines labeled with bacterial G6PDH (0.72 U/mL),* Tris buffer, bovine serum albumin, preservatives, and stabilizers	12 mL/ 50 mL/ 435 mL

****The antibody titer and enzyme conjugate activity may vary from lot to lot.***

Note: Reagents 1 and 2 are provided as a matched set. They should not be interchanged with components of kits with different lot numbers.

Risk and Safety

Safety data sheets (MSDS/SDS) available on siemens.com/healthcare

Precautions

Contains sodium azide (<0.1%) as a preservative. Sodium azide can react with copper or lead pipes in drain lines to form explosive compounds. Dispose of properly in accordance with local regulations.

For *in vitro* diagnostic use.

The Emit® II Plus Amphetamines Assay reagents are provided liquid, ready to use, and may be used directly from the refrigerator. Close the reagent bottles when not in use.

Note: Caps must always be replaced on the original containers.

When not in use, reagents must be stored at 2–8°C (36–46°F), upright, and with screw caps tightly closed. If stored as directed, reagents are stable until the expiration date printed on the label. Refer to the application sheet for on-instrument stability information. Do not freeze reagents. Avoid prolonged exposure to temperatures above 32°C (90°F). **Improper storage of reagents can affect assay performance.**

5 Specimen Collection and Preparation

- Urine specimens may be collected in plastic (i.e., polypropylene, polycarbonate, polyethylene) or glass containers. Some plastics can adsorb certain drugs.
- Internal testing has shown that, if not analyzed immediately, specimens may be stored unrefrigerated for up to 7 days. Specimens may be stored refrigerated for 30 days before analysis. After 7 days unrefrigerated or 30 days refrigerated, samples should be stored frozen.
- Frozen specimens must be thawed and mixed thoroughly prior to analysis.
- Specimens with high turbidity should be centrifuged before analysis.
- Urine specimens within the pH range of 3 to 11 do not require prior pH adjustment.
- Adulteration of the urine specimen may cause erroneous results. If adulteration is suspected, obtain another specimen.
- Human urine specimens should be handled and treated as if they were potentially infectious.

6 Procedure

Materials Provided

Emit® II Plus Amphetamines Assay
Antibody/Substrate Reagent 1
Enzyme Reagent 2

Materials Required But Not Provided

9A509UL	Emit® Calibrator/Control Level 0
9A529UL	Emit® Calibrator/Control Level 1
9A549UL	Emit® Calibrator/Control Level 2
9A569UL	Emit® Calibrator/Control Level 3
9A609UL	Emit® Calibrator/Control Level 5

Commercial controls

The use of d-amphetamine controls with the 1000 ng/mL cutoff is not recommended. Recovery and performance of d-amphetamine and d-methamphetamine are not equivalent above 1100 ng/mL.

Instruments

Siemens Healthcare Diagnostics provides instructions for using this assay on a number of chemistry analyzers. Contact the Technical Assistance Center in the USA or your local Siemens representative for application sheets.

Analyzers must be capable of maintaining a constant reaction temperature, pipetting specimens/reagents and measuring enzyme rates precisely, timing the reaction accurately, and mixing reagents thoroughly.

Assay Sequence

To run the assay, see the instrument operator's manual and the application sheets available from Siemens.

Calibration

Note: These reagents are qualified for use with Emit® Calibrators/Controls only. However, other control material may be used for quality control purposes.

Table 1 — d-Methamphetamine Concentrations in Emit® Calibrators/Controls for Use in Qualitative or Semiquantitative Analysis

Cutoff Calibrator/Control (ng/mL)	Additional Recommended Calibrators/Controls for Qualitative Analysis (ng/mL)	Required Calibrators/Controls for Semiquantitative Analysis (ng/mL)
300 (Level 1)	Level 0 (0) Level 5 (2000)	Level 0 (0) Level 1 (300) Level 2 (500) Level 3 (1000)
500 (Level 2)	Level 0 (0) Level 5 (2000)	Level 0 (0) Level 1 (300) Level 2 (500) Level 3 (1000)
1000 (Level 3)	Level 0 (0) Level 5 (2000)	Level 0 (0) Level 1 (300) Level 2 (500) Level 5 (2000)

Note: For any individual cutoff level, a calibrator/control is used as a calibrator or as a control when the assay is used for qualitative analysis. When a calibrator/control is used as a calibrator for an individual cutoff level, the other level calibrators/controls (above or below it, as listed above) are used as controls.

Qualitative Analysis

Calibrate by running the appropriate Emit® Calibrator/Control Level for the desired cutoff listed in Table 1. Validate the calibration by running controls (see Quality Control). Refer to the Emit® Calibrators/Controls instructions for use and the application sheet for additional information and instrument settings. Recalibrate as indicated by control results.

Semiquantitative Analysis

Prepare a calibration curve by running the appropriate Emit® Calibrators/Controls listed in Table 1. Validate the calibration by running controls (see Quality Control). Refer to the Emit® Calibrators/Controls instructions for use and the application sheet for additional information and instrument settings. Recalibrate as indicated by control results.

Quality Control

Qualitative Analysis

Refer to Table 1 for the desired cutoff. Validate the calibration by assaying controls. Ensure that the result from Emit® Calibrator/Control Level 0 (0 ng/mL) or Emit® Calibrator/Control Level 5 (2000 ng/mL) relates appropriately to the result from the cutoff calibrator. That is,

- If Emit® Calibrator/Control Level 0 (0 ng/mL) was run, ensure that the result is negative relative to the selected cutoff calibrator level.
- If Emit® Calibrator/Control Level 5 (2000 ng/mL) was run, ensure that the result is positive relative to the selected cutoff calibrator level.

Once the calibration is validated, run urine specimens.

Semiquantitative Analysis

Validate the calibration curve by assaying commercial controls. Ensure that control results fall within acceptable limits as defined by your laboratory.

Once the calibration curve is validated, run urine specimens.

Qualitative and Semiquantitative Analysis

1. Follow government regulations or accreditation requirements for quality control frequency. At least once each day of use, analyze two levels of Quality Control (QC) material with known Methamphetamine or Amphetamine concentrations. Follow your laboratory internal QC procedures if the results obtained are outside acceptable limits.
2. Refer to the instrument operator's manual for appropriate instrument checks.

7 Results

Qualitative Analysis

Refer to Table 1 for the appropriate cutoff Emit® Calibrator/Control. Table 1 contains the concentration of d-methamphetamine present in the Emit® Calibrator/Control selected as a cutoff for distinguishing "positive" from "negative" specimens.

Positive Results. A specimen that gives a change in rate value greater than or equal to the Emit® Calibrator/Control cutoff rate value is interpreted as positive.

Negative Results. A specimen that gives a change in rate value less than the Emit® Calibrator/Control cutoff rate value is interpreted as negative: Either the specimen does not contain amphetamines or amphetamines are present in concentrations below the cutoff level for this assay.

Semiquantitative Analysis

The semiquantitation of positive results enables the laboratory to determine an appropriate dilution of the specimen for confirmation by GC/MS. Semiquantitation also permits the laboratory to establish quality control procedures and assess control performance. Refer to the Analytical Recovery section for the semiquantitative range.

Using the Emit® II Plus Amphetamines Assay, it is possible to make semiquantitative determinations of amphetamines. An estimate of relative total drug concentrations may be obtained by running the appropriate Emit® Calibrators/Controls: Levels 0 (0 ng/mL), 1 (300 ng/mL), 2 (500 ng/mL), 3 (1000 ng/mL), 5 (2000 ng/mL). Refer to the application sheet for instructions.

Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

Siemens has validated use of these reagents on various analyzers to optimize product performance and meet product specifications. User defined modifications are not supported by Siemens as they may affect performance of the system and assay results. It is the responsibility of the user to validate modifications to these instructions or use of the reagents on analyzers other than those included in Siemens Application Sheets or these instructions for use.

8 Limitations

- The assay is designed for use only with human urine.
- A positive result from the assay indicates the presence of amphetamines but does not indicate or measure intoxication.
- There is a possibility that substances and/or factors not listed (e.g., technical or procedural errors) may interfere with the test and cause false results.
- Interpretation of results must take into account that urine concentrations can vary extensively with fluid intake and other biological variables.
- Immunoassays that produce a single result in the presence of a drug and its metabolites cannot fully quantitate the concentration of individual components.
- Boric acid is not recommended as a preservative for urine.

9 Expected Values

When the Emit® II Plus Amphetamines Assay is used as a qualitative assay the amount of drugs and metabolites detected by the assay in any given specimen cannot be estimated. The assay results distinguish between positive and negative specimens—positive indicating specimens that contain amphetamines.

When used semiquantitatively, the assay yields approximate, cumulative concentrations of the drugs or drug metabolites detected by the assay (see Section 7, Results).

10 Specific Performance Characteristics

The data appearing in this section were collected on the SYVA® 30R Biochemical System using the Emit® II Plus Amphetamines Assay. Different sample sizes were used to collect the data in the 300 cutoff subsection versus the 500 and 1000 ng/mL cutoff subsections. See the application sheet for each analyzer for appropriate sample sizes. The urine specimens for the 1000 ng/mL cutoff were also assayed using the Emit® II Plus Monoclonal Amphetamine/Methamphetamine Assay (comparative method). All samples positive and negative were analyzed by GC/MS.

300 ng/mL Cutoff

Accuracy

Qualitative Results

One hundred twenty-four (124) specimens were analyzed by the Emit® II Plus Amphetamines Assay and the reference method (GC/MS). Sixty-two (62) specimens showed positive results by both methods and 58 samples showed negative results by both methods. Data are summarized in Tables 2 and 3. All positive specimens with both methods were positive by GC/MS according to our guideline of amphetamine plus methamphetamine ≥300 ng/mL.

Table 2 — Accuracy of Qualitative Results for the 300 ng/mL Cutoff

		GC/MS +	GC/MS −
Emit® II Plus Amphetamines Assay	+	62	0
	−	4	58

Table 3 — Discrepant Results

Sample Rate (mAU/min)	GC/MS (ng/mL) Amphetamine	GC/MS (ng/mL) Methamphetamine
380	9	311
400	70	275
390	67	255
407	131	214

Cutoff calibrator rate (mAU/min) = 411

Analytical Recovery

Qualitative Results

In qualitative spike analysis, the Emit® II Plus Amphetamines Assay correctly identified the mean rate of spiked specimens containing less than 300 ng/mL of d-amphetamine or d-methamphetamine as negative, and the mean rate of spiked specimens containing greater than 300 ng/mL of d-amphetamine or d-methamphetamine as positive.

Semiquantitative Results

Negative human urine was spiked with concentrations of d-amphetamine at levels throughout the semiquantitative range of 100 to 625 ng/mL. Negative human urine was also spiked with concentrations of d-methamphetamine at levels throughout the semiquantitative range of 150 to 1000 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Amphetamines Assay. Semiquantitative results are shown in Tables 4 and 5.

Table 4 — d-Amphetamine Spiked Sample Semiquantitative Analysis (300 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
100	114	114
200	194	97
250	239	95
330	323	98
500	543	109
625	711	114

Table 5 — d-Methamphetamine Spiked Sample Semiquantitative Analysis (300 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
150	158	105
225	214	95
270	259	96
330	315	96
500	513	103
750	726	97
1000	1002	100

Precision

Precision was determined by assaying calibrators and controls for 20 days, 2 runs per day in replicates of 2 (N = 80). Precision data were calculated according to the National Committee of Clinical Laboratory Standards (NCCLS) Guideline EP5-A (February 1999). Results are summarized in Tables 6 and 7.

Table 6 — Qualitative Analysis of Precision (300 ng/mL cutoff)

Controls/Calibrators (ng/mL)	Mean (mAU/min)	SD	CV (%)	Controls/Calibrators (ng/mL)	Mean (mAU/min)	SD	CV (%)
Within-Run Precision							
d-Methamphetamine				**d-Amphetamine**			
225	380	1.6	0.4	225	380	1.7	0.4
300	410	1.0	0.2	300	414	1.2	0.3
375	444	1.2	0.3	375	449	1.4	0.3
Total Precision							
d-Methamphetamine				**d-Amphetamine**			
225	380	2.1	0.5	225	380	2.7	0.7
300	410	1.7	0.4	300	414	1.9	0.5
375	444	1.7	0.4	375	449	2.1	0.5

Table 7 — Semiquantitative Analysis of Precision (300 ng/mL cutoff)

Controls/Calibrators (ng/mL)	Mean (ng/mL)	SD	CV (%)	Controls/Calibrators (ng/mL)	Mean (ng/mL)	SD	CV (%)
Within-Run Precision							
d-Methamphetamine				**d-Amphetamine**			
225	243	1.9	0.8	225	243	2.7	1.1
300	298	2.0	0.7	300	306	2.5	0.8
375	380	3.5	0.9	375	395	4.4	1.1
Total Precision							
d-Methamphetamine				**d-Amphetamine**			
225	243	3.1	1.3	225	243	4.5	1.8
300	298	3.3	1.1	300	306	3.8	1.3
375	380	5.1	1.4	375	395	6.8	1.7

500 ng/mL Cutoff

Accuracy

Qualitative Results

One hundred twenty-four (124) specimens were analyzed by the Emit® II Plus Amphetamines Assay and the reference method (GC/MS). Fifty-eight (58) specimens showed positive results by both methods and 61 samples showed negative results by both methods. Data are summarized in Tables 8 and 9. All positive specimens with both methods were positive by GC/MS according to the new proposed SAMHSA confirmatory guidelines by the following criteria: ≥250 ng/mL methamphetamine and ≥100 ng/mL amphetamine or ≥250 ng/mL amphetamine regardless of the methamphetamine concentration.[7]

Table 8 — Accuracy of Qualitative Results for the 500 ng/mL Cutoff

		GC/MS +	GC/MS −
Emit® II Plus Amphetamines Assay	+	58	4
	−	1	61

Table 9 — Discrepant Results

Sample Rate (mAU/min)	GC/MS (ng/mL) Amphetamine	GC/MS (ng/mL) Methamphetamine
431	64	598
428	48	528
420	50	577
421	63	556
406	245	421

Cutoff calibrator rate (mAU/min) = 419

Analytical Recovery

Qualitative Results

In qualitative spike analysis, the Emit® II Plus Amphetamines Assay correctly identified the mean rate of spiked specimens containing less than 500 ng/mL of d-amphetamine or d-methamphetamine as negative, and the mean rate of spiked specimens containing greater than 500 ng/mL of d-amphetamine or d-methamphetamine as positive.

Semiquantitative Results

Negative human urine was spiked with concentrations of d-amphetamine at levels throughout the semiquantitative range of 150 to 1100 ng/mL. Negative human urine was also spiked with concentrations of d-methamphetamine at levels throughout the semiquantitative range of 200 to 1800 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Amphetamines Assay. Semiquantitative results are shown in Tables 10 and 11.

Analytical Recovery of Semiquantitative Results

Table 10 — d-Amphetamine Spiked Sample Semiquantitative Analysis (500 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
150	168	112
225	219	97
300	275	92
450	441	98
550	537	98
750	795	106
900	959	107
1100	1200	109

Table 11 — d-Methamphetamine Spiked Sample Semiquantitative Analysis (500 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	210	105
250	243	97
330	309	94
500	498	100
750	743	99
1100	1033	94
1500	1443	96
1800	1712	95

Precision

Precision was determined by assaying calibrators and controls for 20 days, 2 runs per day in replicates of 2 (N = 80). Precision data were calculated according to the National Committee of Clinical Laboratory Standards (NCCLS) Guideline EP5-A (February 1999). Results are summarized in Tables 12 and 13.

Table 12 — Qualitative Analysis of Precision (500 ng/mL cutoff)

Controls/Calibrators (ng/mL)	Mean (mAU/min)	SD	CV (%)	Controls/Calibrators (ng/mL)	Mean (mAU/min)	SD	CV (%)
Within-Run Precision							
d-Methamphetamine				**d-Amphetamine**			
375	379	1.7	0.4	375	378	1.8	0.5
500	416	1.7	0.4	500	413	1.5	0.4
625	450	1.9	0.4	625	452	1.3	0.3
Total Precision							
d-Methamphetamine				**d-Amphetamine**			
375	379	2.2	0.6	375	378	2.5	0.7
500	416	2.6	0.6	500	413	2.4	0.6
625	450	2.3	0.5	625	452	2.2	0.5

Table 13 — Semiquantitative Analysis of Precision (500 ng/mL cutoff)

Controls/Calibrators (ng/mL)	Mean (ng/mL)	SD	CV (%)	Controls/Calibrators (ng/mL)	Mean (ng/mL)	SD	CV (%)
Within-Run Precision							
d-Methamphetamine				**d-Amphetamine**			
375	377	4.7	1.3	375	371	5.4	1.5
500	501	6.3	1.3	500	489	5.5	1.1
625	655	10.1	1.6	625	668	8.3	1.2
Total Precision							
d-Methamphetamine				**d-Amphetamine**			
375	377	6.4	1.7	375	371	8.6	2.3
500	501	9.4	1.9	500	489	8.1	1.7
625	655	12.0	1.8	625	668	10.7	1.6

1000 ng/mL Cutoff

Accuracy

Qualitative Analysis

One hundred twenty-four (124) specimens were analyzed by the Emit® II Plus Amphetamines Assay and the Emit® II Plus Monoclonal Amphetamine/Methamphetamine Assay (predicate method). Fifty-nine (59) specimens showed positive results by both methods and 61 samples showed negative results by both methods. Three (3) specimens were positive by the Emit® II Plus Amphetamines Assay and negative by the predicate method. One (1) specimen was negative by the Emit® II Plus Amphetamines Assay and positive by the predicate method. Data are summarized in Tables 14 and 15. All specimens positive by both methods were shown to be positive for amphetamines by GC/MS although the ratios of methamphetamine to amphetamine were not consistent with SAMHSA confirmatory guidelines.[1] Fifty (50) of the 61 specimens shown to be negative by both methods were negative for amphetamines by GC/MS.

Table 14 — Accuracy of Qualitative Results

		Predicate Method +	Predicate Method −
Emit® II Plus Amphetamines Assay	+	59	3
	−	1	61

Table 15 — Discrepant Results

Qualitative (mAU/min)	Semiquantitation (ng/mL)		GC/MS (ng/mL)	
Emit® II Plus Amphetamines Assay	Emit® II Plus Amphetamines Assay	Predicate Method	Amphetamine	Methamphetamine
488	1022	905	850	325
481	910	1004	106	995
508	<2000	981	1357	0
495	1200	891	767	508

Cutoff calibrator rate (mAU/min) = 486

One hundred twenty-four (124) specimens were analyzed by the Emit® II Plus Amphetamines Assay and GC/MS (reference method). Fifty-five (55) specimens showed positive results by both methods and 52 samples showed negative results by both methods. Data are summarized in Tables 16 and 17. All positive specimens with both methods were positive by GC/MS according to the SAMHSA requirements by the following criteria: ≥500 ng/mL methamphetamine and ≥200 ng/mL amphetamine or ≥500 ng/mL amphetamine regardless of the methamphetamine concentration.[1]

Table 16 — Accuracy of Qualitative Results

		GC/MS +	GC/MS −
Emit® II Plus Amphetamines Assay	+	55	7
	−	10	52

Table 17 — Discrepant Results

Qualitative (mAU/min)	Semiquantitation (ng/mL)	GC/MS (ng/mL)	
Emit® II Plus Amphetamines Assay	Emit® II Plus Amphetamines Assay	Amphetamine	Methamphetamine
476	847	264	574
484	958	323	808
469	778	1032	161
483	944	525	612
479	889	378	667
476	844	238	727
479	884	269	820
470	788	211	641
466	752	211	644
491	1084	166	883
505	1887	180	1412
485	975	884	327
506	1965	180	1201
504	1753	152	1204
512	<2000	178	1196
512	<2000	182	1254
498	1297	14	979

Cutoff calibrator rate (mAU/min) = 486

Analytical Recovery

Qualitative Results

In qualitative spike analysis, the Emit® II Plus Amphetamines Assay correctly identified the mean rate of spiked specimens containing less than 1000 ng/mL of d-amphetamine or d-methamphetamine as negative, and the mean rate of spiked specimens containing greater than 1000 ng/mL of d-amphetamine or d-methamphetamine as positive.

Semiquantitative Results

Negative human urine was spiked with concentrations of d-amphetamine at levels throughout the semiquantitative range of 150 to 1100 ng/mL. Negative human urine was also spiked with concentrations of d-methamphetamine at levels throughout the semiquantitative range of 200 to 1800 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Amphetamines Assay. Semiquantitative results are shown in Tables 18 and 19.

Analytical Recovery of Semiquantitative Results

Table 18 — d-Amphetamine Spiked Sample Semiquantitative Analysis (1000 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
150	168	112
225	219	97
300	275	92
450	441	98
550	537	98
750	795	106
900	959	107
1100	1200	109

Table 19 — d-Methamphetamine Spiked Sample Semiquantitative Analysis (1000 ng/mL cutoff)

Nominal Concentration (ng/mL)	Mean Concentration (ng/mL)	Recovery (%)
200	210	105
250	243	97
330	309	94
500	498	100
750	743	99
1100	1033	94
1500	1443	96
1800	1712	95

Precision

Precision was determined by assaying calibrators and controls for 20 days, 2 runs per day in replicates of 2 (N = 80). Precision data were calculated according to the National Committee of Clinical Laboratory Standards (NCCLS) Guideline EP5-A (February 1999). Results are summarized in Tables 20 and 21.

Table 20 — Qualitative Analysis of Precision (1000 ng/mL cutoff)

Controls/Calibrators (ng/mL)	Mean (mAU/min)	SD	CV (%)	Controls/Calibrators (ng/mL)	Mean (mAU/min)	SD	CV (%)
Within-Run Precision							
d-Methamphetamine				d-Amphetamine			
750	471	1.8	0.4	750	475	1.7	0.4
1000	489	1.5	0.3	1000	496	1.9	0.4
1250	501	1.7	0.3	1250	510	2.2	0.4
Total Precision							
d-Methamphetamine				d-Amphetamine			
750	471	2.8	0.6	750	475	2.6	0.6
1000	489	3.0	0.6	1000	496	3.1	0.6
1250	501	3.1	0.6	1250	510	4.1	0.8

Table 21 — Semiquantitative Analysis of Precision (1000 ng/mL cutoff)

Controls/Calibrators (ng/mL)	Mean (ng/mL)	SD	CV (%)	Controls/Calibrators (ng/mL)	Mean (ng/mL)	SD	CV (%)
Within-Run Precision							
d-Methamphetamine				d-Amphetamine			
750	792	16.1	2.0	750	828	15.9	1.9
1000	982	27.1	2.8	1000	1126	38.7	3.4
1250	1219	43.3	3.6	1250	1670	174.1	10.4
Total Precision							
d-Methamphetamine				d-Amphetamine			
750	792	21.6	2.7	750	828	21.6	2.6
1000	982	35.5	3.6	1000	1126	55.7	4.9
1250	1219	65.4	5.4	1250	1670	229.5	13.7

Specificity

The Emit® II Plus Amphetamines Assay detects amphetamine compounds in human urine.

Data found in the following tables are representative of the performance of this assay. However, results may vary among reagent lots.

Table 22 lists the concentrations of amphetamine compounds that produce a result that is approximately equivalent to the 300 ng/mL, 500 ng/mL, and 1000 ng/mL calibrator/control cutoffs. Each concentration represents the reactivity level for the stated compound when it is added to a negative urine specimen. These concentrations are within the range of the levels found in urine following use of the compound or, in case of metabolites, the parent compound. If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in Table 22 may combine to produce a rate approximately equivalent to or greater than that of the cutoff calibrator.

Table 22 — Concentrations of Amphetamines that Produce a Result Approximately Equivalent to the 300 ng/mL, 500 ng/mL, and 1000 ng/mL Amphetamine Cutoffs

	Concentration (ng/mL) Giving a Response Approximately Equivalent to the Cutoff		
Compounds	300 ng/mL Cutoff	500 ng/mL Cutoff	1000 ng/mL Cutoff
d,l-4-Methylamphetamine	4400	10200	16500
d-Amphetamine	300	500	1000
d,l-Methamphetamine	450	700	2100
d,l-Amphetamine	625	1050	2150
l-Methamphetamine	725	1325	3650
l-Amphetamine	3450	3750	11500
1,3 Dimethylpentylamine*	3400	5500	14900
MDA	1100	1700	6500
MDMA	5200	9150	34300
MDEA	4400	6800	27200

*Methylhexanamine

Table 23 lists the concentrations of compounds that produce a result that is approximately equivalent to the 300 ng/mL, 500 ng/mL, and 1000 ng/mL cutoffs. Each concentration represents the reactivity level for the stated compound when it is added to a negative urine specimen. Most of the compounds react at levels much higher than typically found in urine (but which may occasionally occur).[5,8] If a specimen contains more than one compound detected by the assay, lower concentrations than those listed in Table 23 may combine to produce a rate approximately equivalent to or greater than that of the cutoff calibrator.

Table 23 — Concentrations of Compounds that Produce a Result Approximately Equivalent to the 300 ng/mL, 500 ng/mL, and 1000 ng/mL Amphetamine Cutoffs

	Concentration (µg/mL) Giving a Response Approximately Equivalent to the Cutoff		
Compounds	**300 ng/mL Cutoff**	**500 ng/mL Cutoff**	**1000 ng/mL Cutoff**
4-Chloramphetamine	2.6	4.5	12.2
Benzphetamine*	0.4	0.7	1.0
Bupropion	250	500	2220
Chloroquine	2100	2200	4500
erythro-Dihydrobupropion	20	32	82
Donepezil	6.4	10.2	11.2
l-Ephedrine	400	800	3500
Fenfluramine	25	40	150
Isometheptene	16	29	56
Mephentermine	8	15	60
Methoxyphenamine	90	160	360
Nor-pseudoephedrine	40	70	170
Phenmetrazine	2.3	3.5	13.0
Phentermine	5.8	9.0	25.0
Phenylpropanolamine	700	1000	2000
Propranolol	100	125	500
d,l-Pseudoephedrine	1400	2600	8300
Quinacrine	2500	3800	16500
Tranylcypromine	30	60	200
Tyramine	150	200	600

Benzphetamine metabolizes to amphetamine and methamphetamine.

Note: Selegiline, a prescription medication used in the treatment of Parkinson's disease, metabolizes to l-amphetamine and l-methamphetamine. Therefore, patients taking Selegiline may test positive by amphetamine assays.

Table 24 lists the compounds that produce a negative result by the Emit® II Plus Amphetamines Assay. Specificity testing was performed at the 300, 500, and 1000 ng/mL cutoffs. Positive results for compounds structurally unrelated to amphetamines have not been observed.

Table 24 — Concentrations of Compounds Showing a Negative Response

Compound	**300 ng/mL Cutoff (µg/mL)**	**500 ng/mL Cutoff (µg/mL)**	**1000 ng/mL Cutoff (µg/mL)**
Acetaminophen	1000	1000	1000
α-Acetyl-*N*,*N*-dinormethadol (dinor LAAM)	25	25	25
l-α-Acetylmethadol (LAAM)	25	25	25
N-Acetylprocainamide (NAPA)	400	400	400
Acetylsalicylic Acid	1000	1000	1000
Albuterol	1000	1000	1000
p-Aminobenzoic Acid (PABA)	1000	1000	1000
Amitriptyline	1000	1000	1000
Amoxicillin	1000	1000	1000
Atenolol	1000	1000	1000
Benzoylecgonine	1000	1000	1000
Buprenorphine	1000	1000	1000
Caffeine	1000	1000	1000
Carbamazepine	250	250	250
Carisoprodol	1000	1000	1000
Chlorpheniramine	1000	1000	1000
Chlorpromazine	200	200	200
Cimetidine	1000	1000	1000
Clomipramine	2.5	2.5	2.5
Clonidine	1000	1000	1000
Codeine	500	500	500
l-Cotinine	100	100	100
Cyclobenzaprine	1000	1000	1000
Desipramine	300	500	800
Dextromethorphan	1000	1000	1000
Dextrorphan	280	280	280
Diphenhydramine	1000	1000	1000
Doxepin	1000	1000	1000
Doxylamine	1000	1000	1000
l-Epinephrine	1000	1000	1000
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	1000	1000	1000
Fenoprofen	150	150	150
Fluoxetine	500	500	500
Furosemide	1000	1000	1000
Glutethimide	500	500	500
Haloperidol	500	700	1000
Ibuprofen	1000	1000	1000
Imipramine	750	750	750
Isoxsuprine	300	500	500
Ketamine	100	100	100
Ketoprofen	1000	1000	1000
Ketorolac Tromethamine	1000	1000	1000
Labetalol	750	750	750
Lidocaine	1000	1000	1000
LSD	2.5	2.5	2.5
Meperidine	1000	1000	1000
Mescaline	1000	1500	1500
Methadone	1000	1000	1000
Methaqualone	1500	1500	1500
d,l-Methyldopa	1000	1000	1000
l-Methyldopa	1000	1000	1000
Monoethylglycinexylidide (MEGX)	1000	1000	1000
Morphine	1000	1000	1000
Nalmefene	20	20	20
Naloxone	500	500	500
Naproxen	1000	1000	1000
Nicotinic Acid	500	500	500
Noracetylmethadol (nor LAAM)	25	25	25
11-nor-Δ^9-THC-9-COOH	100	100	100
Nortryptyline	750	750	750
Nylidrin	750	750	750
Ofloxacin	100	100	100

Compound	300 ng/mL Cutoff (µg/mL)	500 ng/mL Cutoff (µg/mL)	1000 ng/mL Cutoff (µg/mL)
Oxazepam	300	300	300
Phencyclidine	1000	1000	1000
Phenelzine	50	100	100
1-Phenylcyclohexylamine (PCA)	50	50	50
Phenytoin (DPH)	1000	1000	1000
Phthalic Acid	1000	1000	1000
1-Piperidinocyclohexane Carbonitrile (PCC)	50	50	50
Procainamide	1000	1000	1000
Promethazine	1000	1000	1000
Propoxyphene	1000	1000	1000
Ranitidine	1000	1000	1000
Scopolamine	500	500	500
Secobarbital	1000	1000	1000
Thioridazine	100	100	100
Tolmetin Sodium	2000	2000	2000
Tramadol	1000	1000	1000
Trazodone	1000	1000	1000
Trifluoperazine	1000	1000	1000
Trimethobenzamide	500	500	500
Trimethoprim	1000	1000	1000
Verapamil	1000	1000	1000
Zidovudine (AZT)	2000	2000	2000
Zolpidem	100	100	100
Sympathomimetic Amines			
Diethylpropion	1000	1000	1000
d,l-Isoproterenol	1000	1000	1000
Metaproterenol	500	500	500
3,4-Methylenedioxypyrovalerone (MDPV)	100	100	100
4-Methylmethcathione (Mephedrone)	100	100	100
Methylone	100	100	100
Methylphenidate (Ritalin®)	1000	1000	1000
Phenethylamine	15	20	20
Phenylephrine	1000	1000	1000
Propylhexedrine	20	30	50
3-OH-Tyramine (dopamine)	300	300	300

Non-Interfering Substances

Each of the following compounds when added to urine containing d-methamphetamine at +/- 25% concentration of the cutoff do not yield a false response relative to the 300, 500, and 1000 ng/mL cutoffs:

Table 25 — Non-Interfering Substances

Compound	Concentration
Acetone	1.0 g/dL
Ascorbic Acid	1.5 g/dL
Bilirubin	2.0 mg/dL
Creatinine	0.5 g/dL
Ethanol	1.0 g/dL
Gamma Globulin	0.5 g/dL
Glucose	2.0 g/dL
Hemoglobin	115 mg/dL
Human Serum Albumin	0.5 g/dL
Oxalic Acid	0.1 g/dL
Riboflavin	7.5 mg/dL
Sodium Chloride	6.0 g/dL
Urea	6.0 g/dL

Sensitivity

The sensitivity level of the Emit® II Plus Amphetamines Assay is 100 ng/mL at the 300 ng/mL cutoff and 150 ng/mL at the 500 and 1000 ng/mL cutoffs. This level represents the lowest concentration of d-methamphetamine that can be distinguished from 0 ng/mL with a confidence level of 95%.

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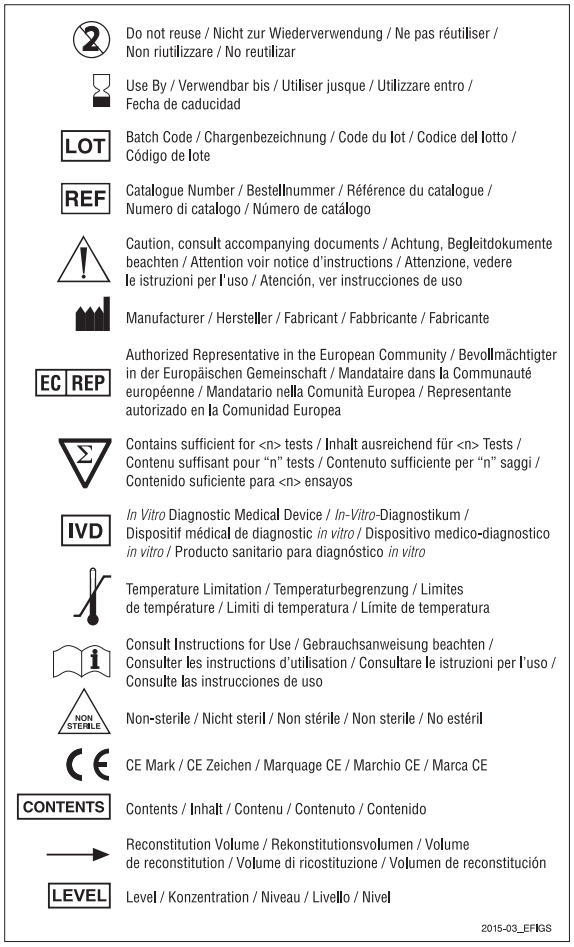
12 Symbols Key



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15 Presentation Information

Good Laboratory Practices

SAMHSA - Substance Abuse and Mental Health Services Administration

Bio Safety

- Gloves, lab coats
- Wear protective eye glasses
- Wash hands
- No application of make-up or lip-balm while testing
- No eating or drinking in testing area

Specimen Handling

- Correctly identify samples
- Label collection cups accurately
  - Name of client
  - Client initials or signature
  - Date and time of collection

Dispose of urine and waste appropriately

Tubes and Pediatric Cups

- Correctly identify samples
- Label calibrator, control, or sample tubes and cups first, then pour or pipette. Do so by one of the following 2 methods:
  - Use bar codes
  - Label appropriately

Appropriate Specimen Storage

Urine:

- It is recommended to store in the refrigerator for up to 30 days.
- May be stored up to 7 days at room temperature.
- Freeze if stored for more than 7 days at room temperature or 30 days refrigerated.
- ETOH samples must be frozen after 3 days per IFU.

Reagent Handling

- Do not mix reagents or different lot numbers.
- Label reagent bottles that are onboard the analyzer with assay name and lot number.
- Mark the date opened on reagent bottles, calibrators and controls.
- Do not use kits or reagents beyond the expiration date.
- Store kits and reagents according to package insert/IFU, typically refrigerated.
- Manage your reagent inventory so the reagent with the earliest expiration date may be used first. For example rotate the newly received product in back of the older product.
- Do not order more supplies than needed especially calibrators or controls.

Basic Procedures

- Use provided tools:
  - *Operator's Manual*
  - *Operator's Quick Reference Guide* (flip chart)
  - *Viva-ProE System Operator Training Workbook*

Basic Operation

- Perform Start of Day / Daily Maintenance
- Calibrate all reagents prior to use.
- Run quality control (QC) prior to running samples.

Results

- Accurately record results.
- Include operator signature or initials, date and time.
- Rerun/confirm all positives.

Calibrations and Controls

Calibrators and Controls

- Packaged as calibrators/controls
- Urine containing known amounts of drug or drug metabolite
- Liquid and ready to use
- Stored between 2°C and 8°C
- Stable until the expiration date on the label (ETOH 4 wks open vial)
- 1 calibrator set for all Emit® II Plus Assays, except 6-AM, Ecstasy, ETOH and Buprenorphine

  Emit II Plus Ecstasy and Emit II Plus 6-AM both use the Emit II Plus Ecstasy 6-AM Cal/Controls Levels 1-4

Calibrations: What You Need to Know

- Every assay needs to be calibrated.
- The calibrator level used is dependent on the assay cutoff value for example Cocaine 150 uses calibrator Level 2.
- Absorbance readings are different for each assay being tested and are NOT cutoff levels.
- Instrument processes calibrators the same as client samples.

Calibrations: How it Works

- Calibrators are run in duplicate, and the average is the stored and reported calibrator absorbance reading.
- Absorbance readings (rates) are obtained and stored by the instrument each time the assay is calibrated and overwrites the previous calibration.

- Calibrator duplicate difference must be less than or equal to 0.015 of each other.
- Client samples are compared to calibration absorbance readings (rates) for each assay.
- Samples results (positive/negative) are compared to the calibrator cutoff level:
  - Results at or above the cutoff level are “presumptive positive” for the drug.
  - Results below the cutoff level are “negative” for the drug.

  Note: Negative does not mean “drug free.”

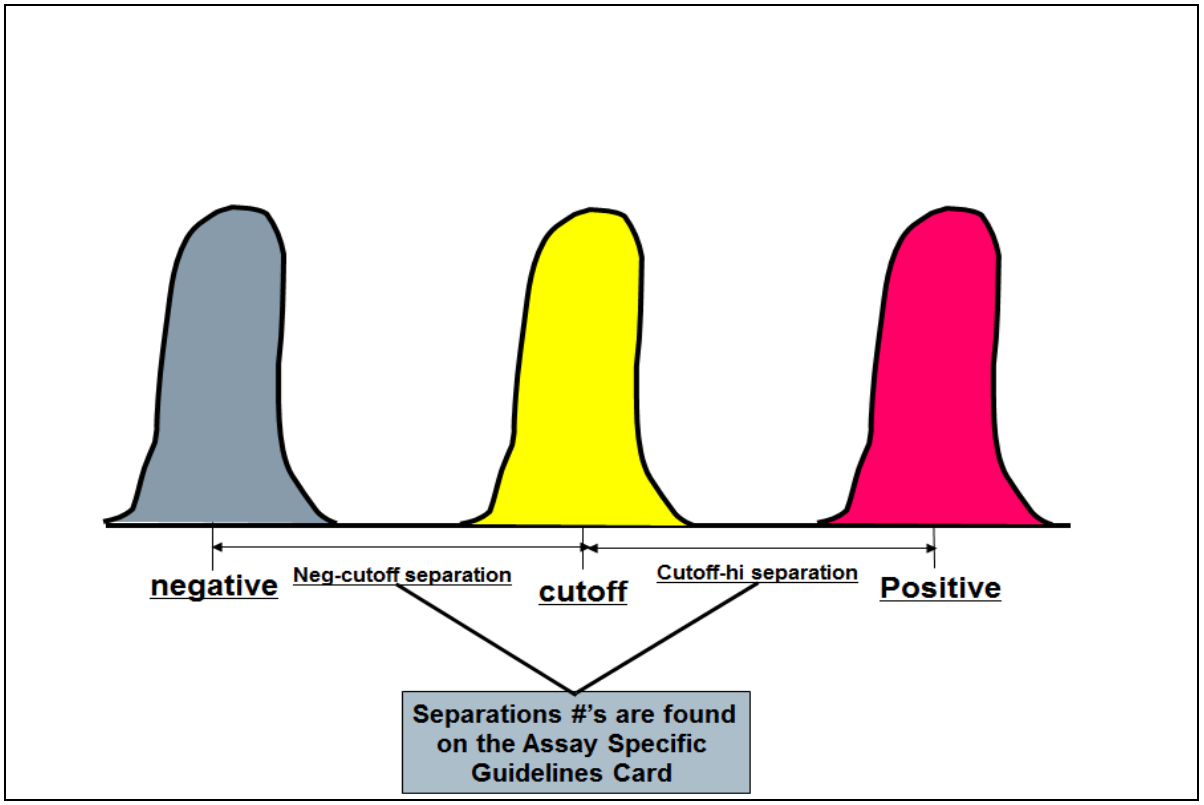
Calibrators and Controls

- Cutoff: The qualitative value of an analyte that is used to decide whether the result or sample is positive or negative
  - Cutoffs for work place drug testing (federally mandated cutoffs) have been set by(Department of Health and Human Services (DHHS)/ and Substance Abuse and Mental Health Services Administration(SAMHSA).
  - Cutoffs for nonregulated drugs are set by manufacturers.

- Pos Control: contains more drug than the Cutoff; higher rate than cutoff and separation must be acceptable for drug or drug metabolite.
- Neg Control: no drug present; rate lower than the cutoff and the separation must be acceptable for drug or drug metabolite.

Evaluating Qualitative Controls

Acceptable Calibration Separations



Separations

- Must be greater than the expected separation found on the assay specific guidelines cards.
- Are calculated by the instrument- for the Positive control by subtracting the cutoff rate from the control rate. For the Negative control by subtracting the control rate from the cutoff rate.
- The bigger the separation, the better.
- The smaller the separation, the greater the chance of false positives or negatives.

  Note: Separations should be consistent from day to day
- Must verify that Level 0 is negative and Level 5 is positive.

Frequency

Calibration: When Do You Calibrate/Recalibrate?

- Establish a routine (lab-dependent; recommendation is once per week)
- With a different lot of reagent
- When control separations are not met (need to be greater than or equal to expected separations)
- After maintenance such as a new lamp, a PM call, a new syringe or when replacing the cuvette rotor

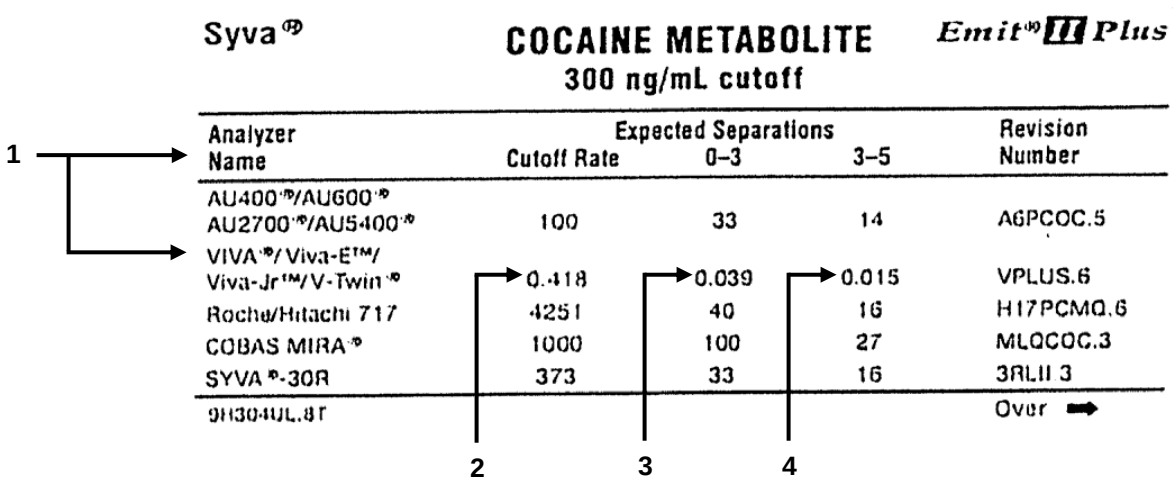
Controls: When Do You Run Controls (QC)?

- Every day after a successful startup and before testing samples
- If multiple shifts, at the beginning of each shift
- After calibration
- Recommended after filling reagent bottles during a run or while testing

  Note: Always run a negative and a positive control
- Run samples only after controls are acceptable

Emit® Generic Lot- Assay Specific Guidelines Card

Example: Emit® II Plus Cocaine Metabolite 300 ng/mL Cutoff Assay



Syva®

COCAINE METABOLITE
300 ng/mL cutoff

Emit® II Plus

Analyzer Name	Expected Separations Cutoff Rate	0–3	3–5	Revision Number
AU400®/AU600® AU2700®/AU5400®	100	33	14	A6PCOC.5
VIVA®/Viva-E™/ Viva-Jr™/V-Twin®	0.418	0.039	0.015	VPLUS.6
Roche/Hitachi 717	4251	40	16	H17PCMQ.6
COBAS MIRA®	1000	100	27	MLQCOC.3
SYVA®-30R	373	33	16	3RLII 3
9H30-4UL.8T				Over ➡

1 2 3 4

1	Analyzer
2	Cal 3 = Cutoff calibrator rate
3	Cal 0 to Cal 3 Separation
4	Cal 3 to Cal 5 Separation

Definitions

Viva: The system used for the V-Twin®, Viva-E®, Viva-Jr® and the Viva-ProE® analyzers.

Cal 3 Cutoff: The level of Emit calibrator used in a qualitative assay calibration. The calibrator level used for the cutoff may vary according to the assay used and the cutoff level. Please refer to the Package Insert and Method-Specific Protocols.

Expected Separations: 0 to 3 is the difference between Cal 0 (negative control) and Cal 3 (cutoff) results. 3 to 5 is the difference between Cal 3 (cutoff) and Cal 5 results. These are the minimum expected separations that are used to validate control results.

Note: Controls results separation should be greater than the “expected separation.”

What is EMIT®?

EMIT® is an acronym for Enzyme Multiplied Immunoassay Technique

Immunoassays

- Immunoassays use antibodies produced by the immune system. Antibodies bind to a specific antigen or closely-related group of antigens.
- The ability to produce antibodies that specifically bind to drugs or their metabolites contributes to antibodies being the principle component of the EMIT® system.
- In EMIT® assays, antibodies are created specifically for drugs or drug metabolites to detect the presence of a specific drug.
- The antibodies are in Reagent 1.

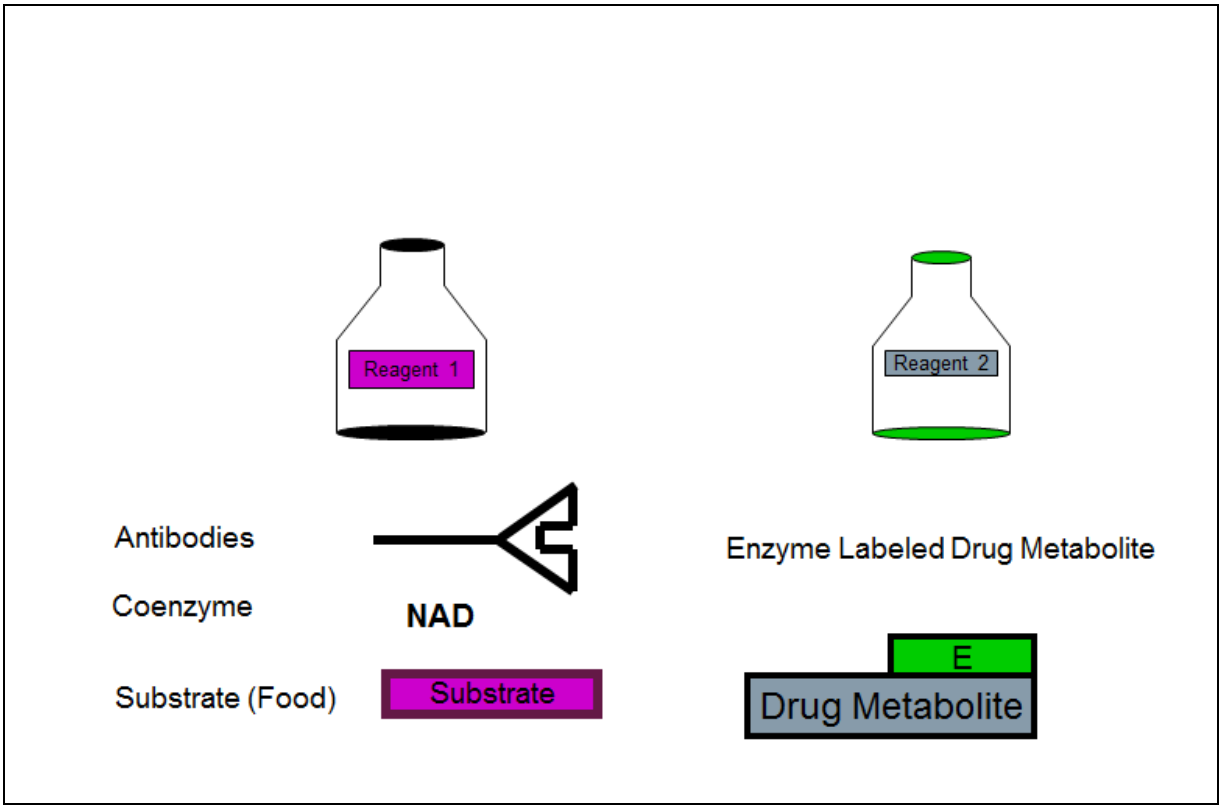
Enzyme Label

- The production of the enzyme-labeled drug is the critical step in the development of an EMIT® assay.
- Enzymes are catalysts for making chemical changes. When provided with a substrate they create color-producing byproducts that can be measured in the reaction.
- The enzyme in Reagent 2 is linked to the same drug or drug metabolite that the antibody is created for and the second key component in the EMIT® reaction.

2 Key points

- Antibodies attack Antigens (The drug).
- Enzymes eat the food (Substrate) to make the reaction happen.

EMIT Reagents



Reagents

Reagent 1

- Antibody
- Substrate (G6P) = Food
- Coenzyme (NAD)
- Buffer

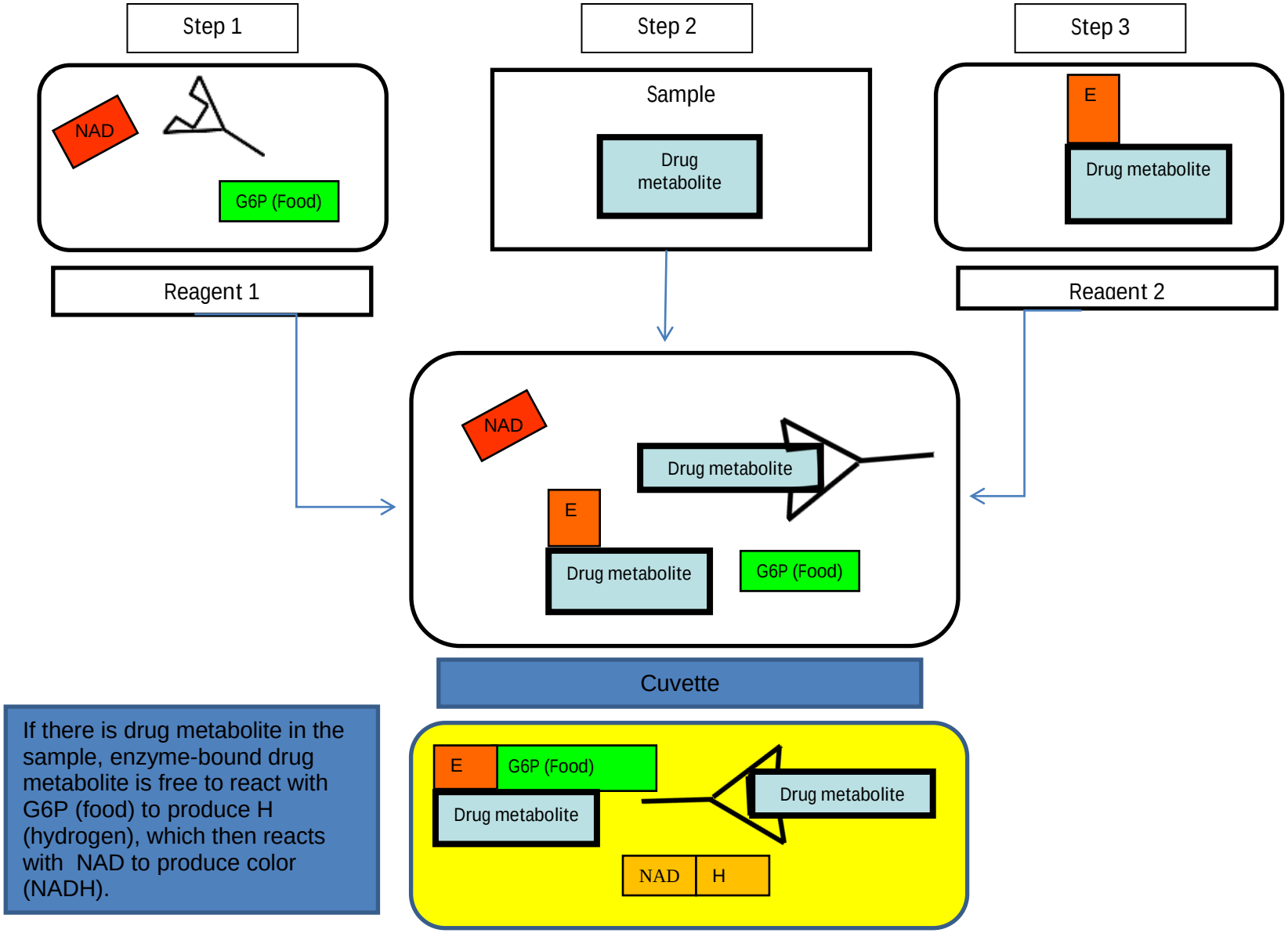
Reagent 2

- Enzyme-labeled drug or drug metabolite
- Buffer

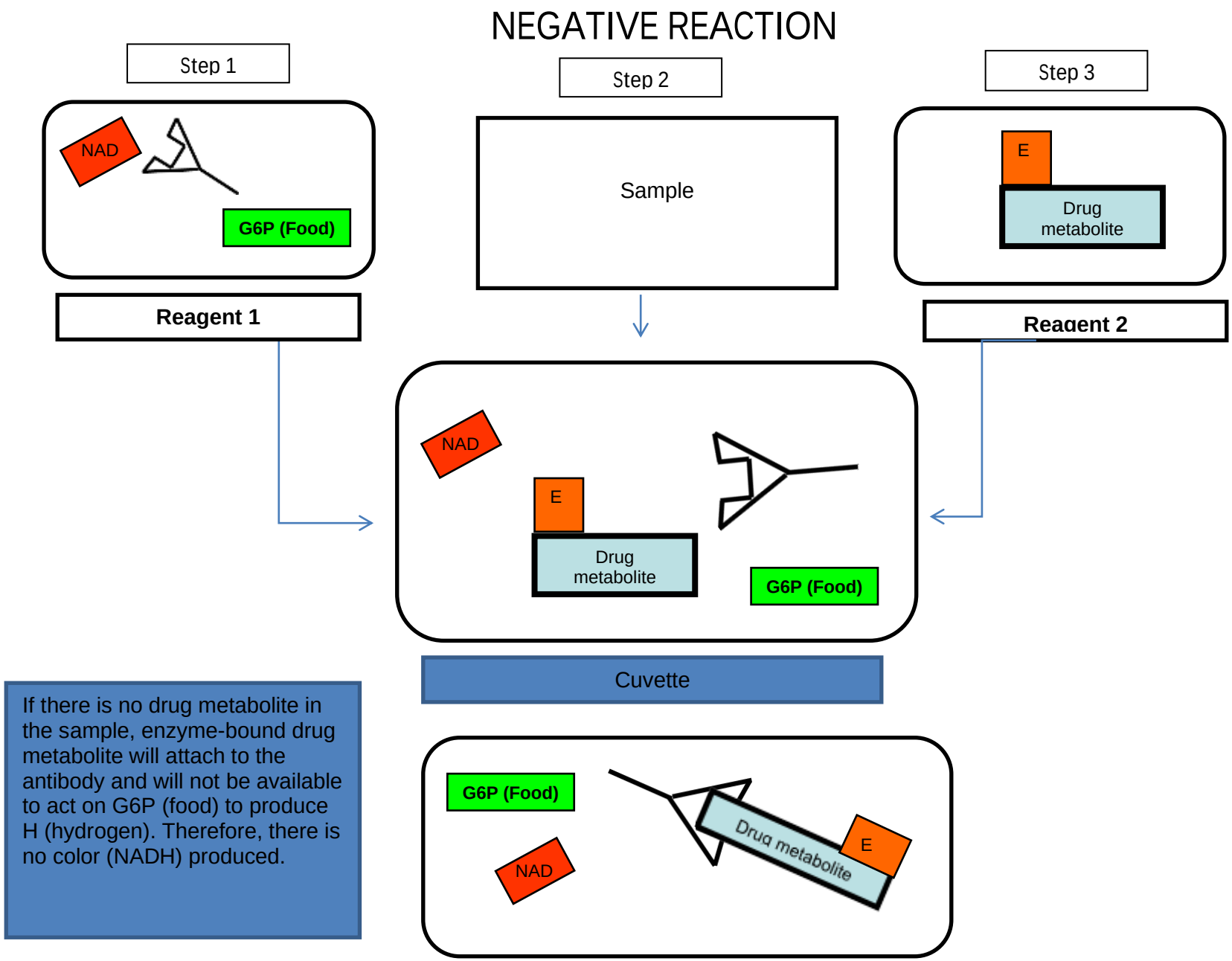
Enzymatic Reaction

- The assays are based on the competition between the drug or drug metabolite in the urine sample and drug labeled with the enzyme (G6PDH) for antibody binding sites.
- When the enzyme-labeled drug reacts with the substrate, it produces hydrogen.
- The co-enzyme NAD (nicotinamide adenine dinucleotide) is converted to NADH. NADH possesses a unique property: it absorbs light at 340 nm and changes in absorbance can be measured photometrically.
- Enzyme activity decreases upon binding to the antibody, so the drug concentration in the urine sample can be measured in terms of enzyme activity.

POSITIVE REACTION



If there is drug metabolite in the sample, enzyme-bound drug metabolite is free to react with G6P (food) to produce H (hydrogen), which then reacts with NAD to produce color (NADH).


NEGATIVE REACTION
Step 1
Step 2
Step 3
NAD
G6P (Food)
Sample
E
Drug metabolite
Reagent 1
Reagent 2
NAD
E
Drug metabolite
G6P (Food)
Cuvette
If there is no drug metabolite in the sample, enzyme-bound drug metabolite will attach to the antibody and will not be available to act on G6P (food) to produce H (hydrogen). Therefore, there is no color (NADH) produced.
G6P (Food)
NAD
Drug metabolite
E

EMIT® Multiplied Reaction in a Positive Sample

When the drug is present in the sample:

- Most of the antibody will bind the drug.
- Less of the antibody will be available to bind with the enzyme.
- More of the enzyme will remain unbound or free.
- Free enzyme will produce more NADH, thus increasing the absorbance of light, at 340nm, in the reaction solution.
- More of the drug leads to more NADH and a higher rate. The NADH is directly proportional to the amount of drug present.

NOTE: The EMIT reaction provides a "presumptive positive" result.

EMIT® Multiplied Reaction in a Negative Sample

When no drug is present in the sample:

- The antibody will bind the enzyme-labeled drug.
- Less of the enzyme will remain unbound or free.
- Very little NADH will be produced, and thus only a small absorbance of light, at 340nm, in the reaction solution.
- Less of the drug leads to less NADH and a lower rate. The NADH is directly proportional to the amount of drug present.

Syva Validity Test (SVT)

Urine Adulteration

Why do people adulterate their urine?

Someone who has added something to their urine to defeat a drug test in all likelihood has been using drugs.

There are 3 ways to adulterate a urine sample:

1. In-vivo adulteration is when the donor ingests something to alter the drug concentration or the urine characteristics in a way that interferes with the drug test.
2. In-vitro adulteration involves tampering with the sample through adding something to the sample. The goal of the additive is to interfere with the drug tests or degrade the drug molecule to where it is not detected by the drug screen and/or confirmation.
3. Substitution includes exchanging the sample with a sample that is drug-free.

Do you think this statement is true?

"Give me 2 hours and a drinking fountain, and I can beat your drug test."

Yes, it is true. Water loading or dilution is the most effective way of interfering with the concentration of drugs in a sample.

- After drinking 0.5 L of water, Creatinine drops from 190 mg/dL to 50 mg/dL in 1 hour
- After drinking 1 L of water, Creatinine drops to 20 mg/dL in 1 hour

A diluted sample is defined as a sample with a Creatinine value less than 20 mg/dL and a specific gravity (sG) value less than 1.003.

In-Vivo (ingests substance to escape detection)

In-vivo products marketed to adulterate a urine sample also come with directions, such as:

- Recommend no "toxins" (drugs) 24 to 72 hours prior to testing
- Use vitamin B-12 or B-complex to restore color
- Typically ingest with a quart to a gallon of water

It is the water that is important. Drinking water is the most effective technique to dilute drug concentration in urine.

In-Vitro (externally adds substance to escape detection)

In-vitro techniques include:

- Diluting the sample with water
- Diluting the sample with common household substances
- Diluting the sample with commercially-marketed products

Substitution

- Concealed container
  - Clean urine in a condom
  - Heat with a hand warmer
- Catheterization
- Take your urine container
- Obtain clean urine:

  From a friend, assuming he/she is not a drug addict

  From a dog

  Buy powdered urine

  Make your own

Prevention Methods

- Removal of bulky clothing such as coats, sweatshirts or remove all clothing if necessary
- Prohibit handbags and briefcases in the restroom where samples or other products may be stored
- Eliminate hot water
- Have Client Wash Hands prior to collection
- Add bluing agent into the toilet
- Removal of soap
- Observed Collection
- Less than 1 hour of time between test notification and collection time
- Limit the amount of water from 8 oz. to 12 oz

Detection Methods

Physical appearance

- Color should be clear or yellow
- Odor should not smell like bleach or ammonia, and so forth
- Temperature: Take immediately. Should be 90.5°F to 98.9°F (32.5°C to 37.7°C)

"Why Should I Test For Adulteration?"

- Mandated by the Department of Transportation
- Mandated by SAMHSA (effective as of 11/01/04)
- Referenced in European Laboratory Guidelines and UK Laboratory Guidelines

Available Syva Validity Products

- pH Validity
- Creatinine Validity
- Specific Gravity Validity
- Nitrite Validity
- Oxidant Validity

Frequently Used Validity Products and Typical Expected Ranges

- pH between 4.5 and 9.0
- Specific gravity between 1.0010 and 1.0250
- Creatinine between 20 mg/dL and 400 mg/dL

Substance Abuse and Mental Health Services Administration (SAMHSA)

Criteria for identifying adulterated samples:

Adulterated: A urine specimen that contains a substance that is not a normal constituent or an endogenous substance at a concentration that is not a normal physiological concentration.

- pH less than 3 or greater than or equal to 11
- Nitrite greater than or equal to 500 µg/L
- Presence of glutaraldehyde, bleach or peroxide (must ID)

- Diluted: A urine specimen with Creatinine and specific gravity values that are lower than expected for human urine. This requires both of the following:
  - Creatinine greater than or equal to 2 mg/dL but less than 20 mg/dL
  - Specific gravity greater than 1.0010, but less than 1.0030

- Substituted: A urine specimen with Creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine. This requires both of the following:
  - Creatinine less than 2mg/dL
  - Specific gravity less than or equal to 1.001, or greater than or equal to 1.0250

Department of Human Health Services (DHHS)

Invalid: A urine specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

The use of validity testing in conjunction with Syva DAT testing is an effective method to achieve a high level of accuracy in a drug test.

16 Resources

Viva Analyzers Consumables List

Part #	Description	Comments
10445339	0.1N HCL (Hydrochloric Acid)	1 L
10445341	0.1N NaOH (Sodium Hydroxide)	1 L
10445223	Sodium Hypochlorite Solution (Needle Rinse)	1 L
10445247	System Solution	1 L
10484938	15 mL Bottle with Lid	20/pkg
10484937	30 mL Bottle with Lid	20/pkg
10445345	Cuvette Reaction Rotor	3/pkg
10445220	Sarstedt Frosted Plastic Tubes (13X75)	500/pkg
10445229	Sample Cup 2 mL	1,000/pkg
357524	Transfer Pipette 3 mL	500/pkg
10720620	Syringe 1 mL (Reagent)	Large
10720619	Syringe 100 µL (Sample)	Small
10332628	Water Filter	1/pkg
10336657	Mixer Belt	1/pkg
10457084	Pediatric Adapter Set	10/pkg
6001-962	Wash Arm Block Assy	1/pkg
10285189	Wash Arm Dryer Block Assy	1/pkg
10452401	Sample Arm Piercing Rod	1/pkg
10452400	Wash Arm Piercing Rod	1/pkg
10452605	Screw for Dry Block Assy	1/pkg

What You Need to Know About Handling Your Reagents

- All reagents have a lot number (for example, A3) and expiration date. Lot numbers should be documented on the reagent bottles that are placed on the analyzer.
- Only open 1 reagent kit at a time. Keep your “kits in use” separately in a bin. When the last of 1 of the reagents is depleted, the kit is history. Discard what is left. They are not used equally.
- When filling the bottles, never fill above the “shoulder.” The level sensing can be affected. For all the Drugs of Abuse Tests, you should get about 140 deliveries when the bottle is filled to the shoulder.
- Be sure to fill the R1 bottle with R1 and the R2 bottle with R2.
- When topping off reagents swirl gently to mix the reagents and allow time for the reagents to equilibrate
- Never top off or refill the onboard bottle with a different lot number.
- The large and small bottles that you pour the reagents into need to be replaced. The maintenance checklist advises to change the bottles monthly. You can document the bottle onboard (BOB) date on the bottle.
- The Creatinine reagent should be capped and placed in the refrigerator at the end of the day. The R1 reagent can be very unstable, and this will extend the stability. When the stability is compromised, the calibrator abs values will be decreased. The Creatinine calibrators are only good for 21 days.
- You do not need that much calibrator and QC in the small sample cups. Up to the first line or a little below is adequate.
- If you need to recalibrate Alcohol, you will need to redispense the Alcohol calibrators and QC due to evaporation.
- When running Alcohol it may be recommended to use tubes not cups for all calibrators, controls and samples
- For Drugs of Abuse testing use polypropylene tubes not polystyrene to reduce THC adherence to the plastic tubes.

Other Important Tips

- Perform Backing up of System Database and Archive Files in case of a computer crash.

GLOSSARY

Absorbance -The amount of light absorbed by matter in solution.

Aliquot - A representative sample of a larger quantity.

Amphetamine - A stimulant, also known as Speed, Ice, Crystal, Amp, Pharmaceutical names include Benzedrine, Dexedrine.

Antibodies - Proteins generated by the immune system in reaction to foreign invaders. They remove the invaders from the system. Each antibody is made specifically to recognize only one invader.

Antibody Binding -The antibody attaches to the matching site on the invader prior to removing it from the body. The Emit assays use antibody binding to recognize drugs.

Audible Alarm -The sound the Viva analyzer uses to alert the operator. Press the space bar to stop the alarm.

Barbiturates - A depressant, also known as downers reds, yellow jackets Pharmaceutical names Amobarbital, Phenobarbital . Used as sedatives, hypnotics.

Benzodiazepine - A depressant also known as bennies Pharmaceutical names Valium, Oxazepam, Xanax (Alprazolam).

Buffer -The buffer contained in the Emit reagents provides a consistent environment in which the test can take place.

Calibrate -To determine, by measurement or comparison with a standard, the correct value of each assay reading.

Calibrator - A sample that contains a known amount of drug or drug metabolite and is used to compare unknown samples with. Calibrators are used as a comparison to measure the drug in a sample much as a ruler is used to measure height.

Cannabinoid (THC) - A hallucinogen also known as marijuana, weed, hash, Pharmaceutical name Marinol.

Carryover - The contamination of one sample on an instrument by a previous sample. Carryover occurs if some of the first sample (typically a sample with a very high concentration of the drug) is carried over by the probe to the next sample causing it to test positive when it should have tested negative

Catalyst - A substance that modifies and increases the rate of a chemical reaction without being consumed in the process.

Cocaine - A stimulant also known as Coke, Crack, nose candy.

Cocaine Metabolite - The substances which the liver breaks cocaine down to, the primary cocaine metabolite is benzolecgonine.

Coenzyme - A heat-stable organic molecule that must be loosely associated with an enzyme for the enzyme to function.

Concentration Units - Units of measurement that tell how much of a solid is suspended or dissolved in a liquid. The Emit tests use nanograms (one billionth of a gram) of drug per milliliter of liquid for units (ng/mL).

Control - A sample that contains either a known amount of drug (positive) or no drug at all (negative) and is used to check the system. The system consists of the analyzer, chemistry (reagents, calibration) and the operator. These control values must meet minimum separation specifications.

Cutoff - The qualitative value of an analyte that is used to decide whether the result or sample is positive or negative

- Cutoffs for work place drug testing (federally mandated cutoffs) have been set by (Department of Health and Human Services (DHHS) / and Substance Abuse and Mental Health Services Administration (SAMHSA).
- Cutoffs for nonregulated drugs are set by manufacturers.

Cutoff Calibrator - Urine or serum standard containing the amount of drug that will serve as the cutoff between positive samples and negative samples.

Cross reactivity -The measure of the assays affinity for a specific drug. This may be affected by protocol, time, temperature and other factors all of which is not clearly understood.

Cuvette rotor - The compartment where the reaction (sample and reagents) occurs and is read by the photometer.

DAT or DAU - Drugs of Abuse Testing or Drugs of Abuse.

Deionized Water - Water from which all charged species or ionizable organic and inorganic salts have been removed via an ion exchange process.

Distilled Water - Water that has been freed of dissolved or suspended solids and organisms by distillation.

Drug of Abuse - A drug that is taken for non-medicinal reasons, usually for mind-altering effects.

EMIT - Enzyme Multiplied Immunoassay Technique

Enzymes - Proteins produced by living organisms that function as biochemical catalysts in living organisms.

Equilibrate -To reach equilibrium, a state in which all acting influences are canceled by others, resulting in a stable, balanced, unchanging system.

Immune Reaction -The reaction of the immune system to a foreign invader, which involves the production of antibodies which bind to and remove the invader from the body.

Immune System – A complex system of cells by which an organism protects itself against foreign pathogens.

Immunoassay - A test that analyzes and identifies a substance on the basis of its antigenic actions.

Lyophilized - Freeze dried.

MDMA Methylenedioxymethamphetamine, Ecstasy - A stimulant also known as Molly, XTC, Adam.

Metabolite - A substance that has been transformed from another substance by the body's metabolic processes.

Methadone - An opioid also known as Fizzie.

Methamphetamine - A stimulant, also known as speed, crystal, crank, and by pharmaceutical names such as Desoxyn and Methedrine.

Methaqualone - A depressant also known as Ludes, Quad, Quay, Pharmaceutical name Quaalude.

Microliter µL - Unit of measurement meaning one millionth of a liter.

Milliliter (mL) - One thousandth of a liter

Molecule -The smallest amount of a substance which can exist alone, a chemical combination of two or more atoms which form a specific chemical substance

NAD - Nicotinamide adenine dinucleotide (NAD) is the substrate upon which the enzyme G6PDH acts. In the Emit technology NAD is converted to NADH. The amount of this reaction is dependent on the amount of drugs in the sample and is measured by the analyzer.

Nanogram (ng) - One billionth of a gram.

Opiate - A sedative narcotic containing opium or one or more of its derivatives, also known as heroin, smack, chasing the tiger. Pharmaceutical names include, morphine, codeine, oxycontin.

Phencyclidine (PCP) - a hallucinogen, also known as Angel Dust, Peace, and Pill. Originally an animal tranquilizer.

Pipette - Small glass or plastic tube, used to transfer small amounts of liquid. Or the act of transferring small amounts of liquid.

Plasma -The clear, yellowish fluid portion of blood in which the particulate components are suspended.

Probe -The part of the analyzer that transfers reagents and samples to a cuvette.

Propoxyphene - An analgesic, sold as Darvon, Darvocet.

Qualitative - The presence or absence of an analyte in a sample.

Quantitative - The concentration or amount of analyte in a sample.

Rate - Change in absorbance over time

Reagent - A substance used to produce a chemical reaction so as to detect measure, or produce other substances.

Reconstitute -To return a freeze-dried substance to its former hydrated state by adding water.

Semi-quantitative - the preliminary concentration of the analyte in the sample, to be confirmed by a more specific alternative chemical method such as Gas chromatography/mass spectrometry.

Sample - Often used interchangeably with *specimen;* urine or blood given by a donor that will be used for testing.

Sample Cup -The small container that holds sample on the instrument.

Sample Identification Number (ID) -The unique number assigned to each sample.

Sample Rotor -The instrument tray that holds the calibrators, controls or sample containers and probe wash.

SAMHSA - Substance Abuse and Mental Health Services Administration, the agency which establishes certification program for laboratories engaged in urine drug testing for Federal agencies. Establishes scientific and technical guidelines for Federal agencies workplace drug testing programs.

Sensitivity -The capability of an antibody to connect with its antigen even when the antigen is present in low concentrations.

Serum -The clear liquid that separates from blood when it is allowed to clot completely, it is therefore blood plasma from which the fibrinogen has been removed in the process of clotting.

Specificity -The special affinity of an antibody for just one antigen, the less likely it is to connect with a different kind of antigen, the more specific it is.

Substrate - A substance upon which an enzyme acts.

Syringe - Aspirates and dispenses sample or reagent.

Ultraviolet light -The range of wavelengths covering 4-400 nanometers (nm), NADH, one of the products of the Emit chemistry when drugs are present, can be detected at 340 nm, the wavelength at which the analyzer reads the reaction.