

Completion Certificate

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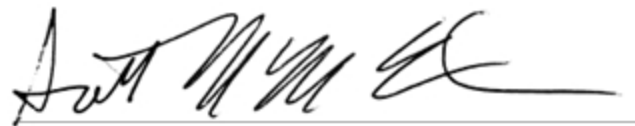
This is to certify that

Valeriu TUGULEA

has completed a course of instruction on:

IMMULITE® 2000 Immunoassay System
Sample Processing Mentor Checklist

Date: 03.11.2024



Scott McCuen Koytek
Global Head of Education
Siemens Healthineers

Completion Certificate

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IMMULITE® 2000 XPi Immunoassay System
Sample Processing Practical Exercise

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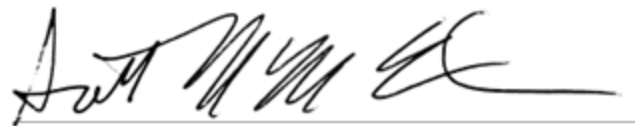
This is to certify that

Valeriu TUGULEA

has completed a course of instruction on:

IMMULITE® 2000 XPi Immunoassay System
System Overview Practical Exercise

Date: 16.06.2022



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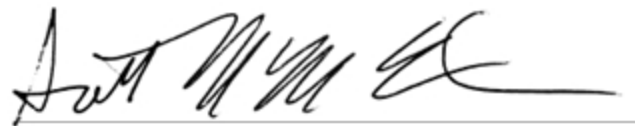
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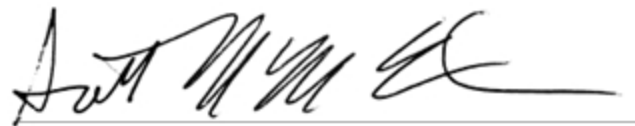
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IMMULITE® 2000 Immunoassay System
Sample Processing Online Training

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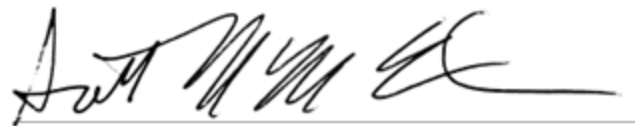
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IMMULITE 2000 System Allergy

A primary Siemens-trained operator or a Siemens representative can use this checklist to observe the operator performing the tasks listed below. The observer places a check mark beside the task when it is completed successfully. Successful completion for each task is determined by the facility. The standards used to evaluate can be documented in the “*Criteria*” section below.

Use the area below to record comments or areas of improvement. If necessary, the observer can record recommended next steps of action for areas of improvement or development opportunities.

When all tasks are checked, the observer and operator sign and date this document as a record of completion.

Criteria: Standards for successful completion of each task (i.e. Accuracy, Time, Quality, etc.).

Tasks	Completed
Identify and load the allergy kit components	
Run allergy adjustors, controls, and patients	

IMMULITE 2000 System
Mentor Checklist

Comments:

Areas of Improvement:

Next Steps:

_____ has successfully performed the above tasks.

Observer: _____

Operator: _____

Date: _____

IMMULITE 2000 XPi System **Sample Processing**

Time Required: 45 minutes

Technical References:

- IMMULITE[®] 2000, IMMULITE[®] 2000 XPi, IMMULITE[®] 2500 Immunoassay Systems Operator's Guide, Operating the System section
- Online Help

Educational References:

Sample Processing Online Training course

Objectives:

Upon completion of this exercise you will be able to perform the following tasks:

- Load and unload samples using the rack loader
- Run patient samples with and without an LIS
- Access the Sample Tubes in Racks screen, Display/Edit screen and Review screen to retrieve sample information
- Order unbarcoded patient samples
- Run patient samples using microsample tubes and tube top cups
- Add a test to a sample in progress
- Assign various worklist options to samples

Supplies Needed:

- Personal Protective Equipment
- QC materials
- DI water for reconstitution of material as needed
- Pipettes for reconstitution
- Test tubes
- Control barcode labels (optional)
- At least 5 barcoded patient samples with LIS orders
- At least 5 barcoded patient samples without LIS orders
- At least 2 unbarcoded patient samples
- Microsample tube holders with tubes
- Tube top sample rack
- Patient samples with tube top cups
- Diluent and a diluent barcode for one of the tests being run on the instrument
- Patient sample to make a manual dilution
- 16 x 100 mm sample tube for onboard diluent

Exercise Activity and Questions

Load and unload samples using the rack loader

1. Load 2 sample racks onto the instrument.

a) How can you tell when it is safe to load a new sample rack onto the instrument?

b) How are sample racks loaded onto the IMMULITE 2000 XPi system?

2. Eject one of the loaded racks from the instrument.

a) What are 2 ways to eject a rack from the instrument?

Run patient samples with LIS orders

1. Locate 5 barcoded samples with LIS orders. Load the samples on the system.

a) When will the system start running these samples?

IMMULITE 2000 XPi System
Practical Exercise

Order barcoded patient samples without an LIS

1. Load five barcoded patient samples that do not have LIS test orders on the system.
2. Order tests on these barcoded patient samples.
 - a) List the steps required to order tests on barcoded patient samples.

3. Access the Display / Edit screen. Select the Update Screen button to display current information.

Identify sample status on the Sample Tubes in Racks screen and the Display/Edit screen

1. Access the Sample Tubes in Racks screen.
 - a) How do you access the Sample Tubes in Racks screen?

- b) What do the different tube position shapes on the Sample Tubes in Racks screen indicate?

- c) How can you access current information on the Sample Tubes in Racks screen?

IMMULITE 2000 XPi System
Practical Exercise

2. Access the Display / Edit screen.

a) How do you access the Display / Edit screen?

b) What will a sample's status be on the Display / Edit screen when it has been pipetted?

c) How can you access current information on the Display / Edit screen?

d) What happens to records on the Display / Edit screen after the test results?

Access Review screen

1. Access the Review screen. Select the Time button to open the Select Time Method window.

a) What options are available in the Select Time Method window?

2. Select to view all results.

a) How many results appear on the screen at a time?

b) Which buttons are used to scroll through different results?

Order unbarcoded patient samples

1. Load two unbarcoded patient samples on the system.

a) How can you tell where unbarcoded tubes are located on the sample carousel?

2. Order tests on these unbarcoded patient samples.

a) Which three pieces of information need to be entered on the Worklist screen to order tests on unbarcoded patient samples?

3. Access the Display / Edit screen. Select the Update Screen button to display current information.

Run patient samples using microsample tubes

1. Load a sample rack with microsample tubes onto the instrument.

2. On the Home screen, select the sample rack with the microsample tubes to display the Rack Detail screen. Select the Sample Tubes button at the bottom of the Rack Detail screen to display the Sample Tubes in Racks screen.

a) Looking at the Sample Tubes in Racks screen, how can you tell where the microsample tubes are on the system?

3. Order tests on the microsample tubes.

a) Is there a difference between ordering tests on standard size tubes and microsample tubes?

Run patient samples using tube top cups

1. Load a tube top sample rack with tube top samples onto the instrument.

a) When would you want to use tube top samples?

b) Looking at the Home screen, how can you tell where the tube top samples are on the system?

2. On the Home screen, select the sample rack with the tube top samples to display the Rack Detail screen. Select the Sample Tubes button at the bottom of the Rack Detail screen to display the Sample Tubes in Racks screen.

a) Looking at the Sample Tubes in Racks screen, how can you tell where the tube top samples are on the system?

3. Order tests on the tube top samples.

a) Is there a difference between ordering tests on standard size tubes and tube top samples?

Add a test to a sample in progress

1. Access the Display / Edit screen. Find a sample with a test that has a time to completion listed as the status. Access the Worklist screen and add an additional test to this sample.

a) How do you add a test to a sample that is in progress?

IMMULITE 2000 XPi System
Practical Exercise

b) Is it possible to order tests from a screen other than the Worklist screen?

Order STATS

1. Select one tube loaded on the system and order a test as a STAT for that tube.

a) How do you order a test as a STAT?

b) How does the system process STAT tests differently than other tests?

Distinguish between primary/secondary tubes

1. Access the Worklist screen.

a) How do you change the tube type designation between primary and secondary tube?

b) How does the system handle primary and secondary tubes differently?

Order onboard dilutions

1. Locate the appropriate diluent and diluent barcode for one of the tests loaded on the system. Label a tube with the diluent barcode and pour diluent into the tube. Load the tube onto the system.

a) How can you determine which diluent needs to be used for a particular test?

IMMULITE 2000 XPi System Practical Exercise

b) What size tube should be used for the diluent?

2. Select one tube loaded on the system and order a test with an onboard dilution for this sample.

a) How do you order tests with onboard dilutions?

Order and prepare manual dilutions

1. Prepare a 1:2 manual dilution of one sample using the appropriate diluent.

a) What must be done to prepare the diluent before it is used to dilute the sample?

2. Load the diluted sample onto the system. Order a test for this sample and assign the manual dilution factor.

a) How do you assign manual dilution factors to samples in the Worklist screen?

Exercise Checklist

Completed	Task
<input type="checkbox"/>	Load and unload samples using rack loader
<input type="checkbox"/>	Run patient samples with and without an LIS
<input type="checkbox"/>	Access the Sample Tubes in Racks screen, Display/Edit screen and Review screen to retrieve sample information
<input type="checkbox"/>	Order unbarcoded patient samples
<input type="checkbox"/>	Run patient samples using microsample tubes and tube top cups
<input type="checkbox"/>	Add a test to a sample in progress
<input type="checkbox"/>	Assign various worklist options to samples

Exercise Completed:

Name: _____

Mentor: _____

Signature: _____

Title: _____

Date: _____

Signature: _____

Exercise Activity Answers

Load and unload samples using rack loader

1.
 - a) To determine if the system is ready for a new rack, view the lights to the left of the rack loader door. A solid red light on the rack loader indicates the instrument is not ready to accept a rack. For example, if the rack loader is full, the light will remain red. A solid green light on the rack indicates the instrument is ready to accept a rack.
 - b) If the rack loader light is green, lift the rack loader door and set the sample rack into the sample tray. Then, close the rack loader door. The instrument automatically loads the rack onto the system.
2.
 - a) There are three screens that have eject buttons that can be used to eject sample racks from the system: Home screen, Rack Detail screen, Sample Tubes in Racks screen.

Run patient samples with LIS orders

1.
 - a) If the system is in Run mode, the system will automatically start running barcoded patient samples with LIS orders.

Order barcoded patient samples without an LIS

2.
 - a) To order barcoded patient tests, first select the Worklist button from the horizontal toolbar. Select the Next button until the appropriate patient record displays on the screen. Select the Test button to view the available tests screen. Select the appropriate test(s) to run, and press OK. Select the Accept Patient button.

Identify sample status on the Sample Tubes in Racks screen and the Display/Edit screen

1.
 - a) To access the Sample Tubes in Racks screen, select the Sample Tubes button from one of the Rack Details screens.
 - b) The shape of the sample tube positions indicates the type of tube.
 - c) Select Update on the top right corner of the screen to display the most current information.

IMMULITE 2000 XPi System
Practical Exercise

2.
 - a) To access the Display/Edit screen, select the Worklist button from the horizontal toolbar and then select the Display/Edit button.
 - b) After a test has been successfully pipetted, the status will indicate the time to completion for that test.
 - c) Select Update Screen on the bottom right corner of the screen to display the most current information.
 - d) Records disappear from the Display / Edit screen after the test results.

Access Review screen

1.
 - a) The options available in the Select Time Method window are to select a date range, today only, or all results.
2.
 - a) Results are listed on the screen for one sample at a time.
 - b) The Previous and Next buttons are used to scroll through different results.

Order unbarcoded patient samples

1.
 - a) The location of unbarcoded tubes can be seen on the Sample Tubes in Racks screen. To access the Sample Tubes in Racks screen, select a rack icon on the Home screen and then the Sample Tubes button on the Rack Detail screen. Unbarcoded tubes will display in the color white on the Sample Tubes in Racks screen.
2.
 - a) The three pieces of information need to be entered on the Worklist screen to order tests on unbarcoded patient samples are: accession number, test, and tube position.

Run patient samples using microsample tubes

2.
 - a) On the Sample Tubes in Racks screen, the microsample tube positions are displayed as squares.

IMMULITE 2000 XPi System *Practical Exercise*

3.

a)

No. The worklist screen is used the same way to order tests on standard size tubes and microsample tubes. Microsample tubes can be either barcoded or unbarcoded. If they are unbarcoded, the tube position must be assigned, the same as for standard size tubes.

Run patient samples using tube top cups

1.

a) On the IMMULITE 2000 XPi System, the dead volume of secondary and primary tubes is 250uL. Using tube top samples is one option for running tests using samples whose volumes are less than 250 µL. The dead volume of tube top cups is 100uL. Tube top samples allow you to pipette a small sample into an approved tube top cup and place the cup back in the original sample tube.

b) On the Home screen, the tube top sample racks will display a lower case letter for the rack identifier.

2.

a) On the Sample Tubes in Racks screen, the tube top sample positions are displayed as a square with the letter "T".

3.

a) No. The worklist screen is used the same way to order tests on standard size tubes and microsample tubes.

Add a test to a sample in progress

1.

a) To add a test to a sample that is in progress, first select the Worklist button from the horizontal toolbar. Next, ensure that Patient is highlighted in blue at the top of the screen. Select the New button to display a blank worklist and enter the accession number for that sample into the accession field. Then select the test button to view the available tests screen. Select the appropriate test(s) to run, and press OK. Finally, select the Accept Patient button to save the record.

b) No. Tests can only be ordered from the Worklist screen. Screens such as the Sample Tubes in Racks screen and the Display/Edit screen are only used to view information.

Order STATS

1.

a) To order a test as a STAT, select STAT on the Worklist screen. Then, select the test name in the Tests Ordered screen. The test name turns red, indicating this test now has a STAT priority. Select Accept Patient.

b) STAT tests take pipetting priority over the other tests.

Distinguish between primary/secondary tubes

1.
 - a) Selecting the primary / secondary tube button on the Worklist screen switches between the two tube type designations.
 - b) A primary tube is a blood collection tube in which the serum is separated from the blood cells by a gel barrier. Selecting this option causes the probe to stop before penetrating the gel barrier. A secondary tube is a sample tube where the serum is aliquotted to a different tube. Selecting this option causes the probe to move further into the tube before aspirating the sample.

Order onboard dilutions

1.
 - a) There are several ways to determine which diluent needs to be used for a particular test. Correct answers include the assay's instructions for use and the Kit screen for that test.
 - b) It is recommended that the diluents are put in 16 x 100 mm tubes.
2.
 - a) To order an onboard dilution, select the Dilution button on the Worklist screen. Then, select the assay. The dilution factor screen appears. Select the desired dilution factor.

Order and prepare manual dilutions

1.
 - a) The diluents are concentrated and must be diluted 1 part diluent to 1.5 parts water before using it to dilute the sample.
2.
 - a) To order a manual dilution, select the Manual Dilution button, type the manual dilution factor, and then select OK.