CHEM.VITROS.15.0 Operation of the 4600 Vitros Analyzer System

PRINCIPLE

The VITROS® 4600 Chemistry System uses VITROS® MicroSlide, MicroTip (MicroImmunoassay), MicroSensor and Intellicheck technologies to perform discrete clinical chemistry tests on serum, urine and cerebral spinal fluid specimens. The design of the analyzer combines mechanical automation with computerized electronics to simplify operations, maintenance, and service. The analyzer is comprised of three separate analyzing areas: the MicroSlide center, the MicroTip Center and the MicroSensor center. The MicroSlide center uses reagents that consist of a microscopically thin layer of dry reagent coated onto polyester film, where a series of complex chemical reactions occur. Large molecules are trapped, when appropriate, and a filtrate is passed on to a reagent layer. When the reaction is complete, analytes migrate to an indicator layer to bind with a dye and create a color complex that is measured using reflectance spectrophotometry. Four types of MicroSlides are available: Colorimetric microslides are read just at the end point by the Reflectometer, Potentiometric microslides are single-use, direct ion-specific electrodes that are read by the Electrometer, Rate assays are formulated for enzyme tests with two-point and multi-point reading protocols and are read by the Reflectometer, and Immuno-assay slides incorporate a label and an antibody and are read by the Reflectometer. The MicroTip Center runs photometric tests with liquid reagents that are ready to use. The reactions in this center are read by the Photometer, either spectrophotometrically or turbidmetrically. The MicroSensor center uses spectrophotometry to determine the quality of the samples by measuring hemolysis, icterus and turbidity. The system also uses Intellicheck Technology, a proprietary technology of Ortho Clinical Diagnostics that is designed to significantly reduce critical errors and minimize operator intervention.

OWNERS:

Hospital based Laboratories

SPECIMEN

Refer to individual VITROS® assay procedures.

REAGENTS

A. MicroSlide reagents
   1. Refer to individual Vitros assay product sheets for test specific reagents included in each slide. Slides are used once for a single test and then discarded.
   2. Cartridges must reach room temperature before removal from their foil protective wrappers and before insertion into the analyzer. A minimum of 30 minutes is required for refrigerated cartridges (Lavender boxes) and 1 hour for frozen cartridges (Blue boxes) with the exception of Sodium. Sodium must be thawed for 2 hours from the freezer and 1.5 hours from the refrigerator.
   3. MicroSlide reagents are stable until the expiration date printed on the box/cartridge when stored in the refrigerator or freezer in the intact aluminum foil package.

4. MicroSlide cartridges that remain in the intact aluminum foil package may be left out at room temperature for up to 24 hours. Do not open the aluminum foil package until ready to load on the analyzer.
5. Record the date and technologists initials on each cartridge prior to loading into the analyzer. Be careful not to write in the barcoded area.
6. See individual assay procedures for testing specifics including: specimen requirements, assay ranges, diluents required for making dilutions and reporting requirements.

B. MicroTip Reagents
1. These reagents are found in yellow boxes and are ready to use and can be loaded directly onto the analyzer from the refrigerator.
2. Record the date and technologists initials on each pack prior to loading into the analyzer. Be careful not to write in the barcoded area.
3. See individual assay procedures for testing specifics including: specimen requirements, assay ranges, diluents required for making dilutions and reporting requirements.

C. Electrolyte Reference Fluid (ERF) and Immuno-Wash Fluid (IWF)
1. Both ERF and IWF need to be at room temperature and well mixed before being used for testing.
2. ERF can be left out for 24 hours at room temperature before being loaded onto the analyzer.
3. IWF is only changed every 72 hours and can be warmed at room temperature for 30 minutes before loading onto the analyzer.

D. MicroSensor Check Fluid
1. Two levels are used weekly to QC the MicroSensor system.
2. Vials are stored at room temperature until expiration date on vials or 90 days after opening, whichever comes first.

EQUIPMENT

A. VITROS® 4600 Chemistry System
B. Electrolyte Reference Fluid Reservoir
C. Pierceable Sample cup caps
D. Universal Sample Trays with and without adapters
E. Sample cups, to include Vitros Microsample cups and Elkay, 13mm EZEE Nest polystyrene sample cups
F. Vitros disposable sample tips
G. Versa Tips
H. Micro Tips
I. Cuvettes
J. Humidity packs
K. Desiccant packs
L. Diluents packs
M. MicroSensor Check Fluids
N. Waste Containers
O. Printer and plain paper

CALIBRATION

See CHEM.VITROS.16.0 Vitros 4600 Calibration Procedure for details.

QUALITY CONTROL

A. See CHEM.VITROS.17.0 Vitros QC Procedure for details.

B. Quality control materials containing measured constituents which stress the range of clinical significance of each test must be run at periodic intervals to ensure that the VITROS® has not fallen out of calibration. Acceptable control limits are determined monthly and these limits are updated in the VITROS® at this time. The VITROS® will then flag any control values that are outside acceptable limits. Actual control results are monitored daily by the technologist and at least monthly by management

PROCEDURE

A. OPERATION OF THE MASTER COMPUTER ELECTRONICS

1. Flat Panel Monitor with Touch Screen
    a. The Status Line at the top, right of the screen displays the status of the entire system (Initializing, Equilibration Environment, Ready for Sampling, Diagnostics Mode and Not Ready for Sample Processing). Directly below the system status is the status of any processing assays (Sampling in progress, Assays in progress, Assays Completed, External Sampling in Process and Internal External Sampling in Progress).
    b. Status Console – Consists of all the Navigation buttons. The Navigation buttons are accessible from every function screen. It also contains the Start Sampling and End Sampling button.
        1. Status – Displays the System Status screen used to quickly identify the status of several subsystems and supply levels.
        2. Samples – Displays the Sample Programming screen used to select assays and program samples
        3. Results – Displays the Results Review screen used to evaluate and manage assay results.
        4. QC – Displays the Quality Control screen used to edit QC parameters and review QC results.
        5. Reagents – Displays the Reagent Management screen used to review and manage the reagent supply.
        6. Diagnostics – Displays the Diagnostics screen used to evaluate system operations and perform periodic maintenance.
        7. Options – Displays the Options & Configuration screen used to set system defaults, customize system features, and perform system services.
        8. V-Docs – Displays the V-Docs screen used to view online documentation for system operation and maintenance.
        9. Conditions – Displays the Conditions Review screen used to view system condition codes.
        10. Subsystem Status – Is located directly above the navigation buttons and indicated whether a subsystem is not operating or is operating outside of a normal state.
        11. Condition Codes – Shows the number and type of condition codes that have not been reviewed; from top to bottom: Attention codes, Action Codes, Malfunction Codes, and Shutdown Codes.

12. LIS Status – Displays icons that indicate communication activity between the system and the LIS.
13. LAS Status – Displays icons that identify the status and activity of the Laboratory Automation System.
14. E-Connectivity – Displays the level and state of e-Connectivity.
15. Access Levels – Indicate if the Key Operator or Service level access is enabled.
16. Sampling Buttons – The Sampling button has two states depending on the sampling status. Touch the Start Sampling button to initiate sampling. Touch End Sampling button to stop the metering process. Metering is halted after the sample currently being metered is complete.
17. Date and Time and Software Version is displayed at the top left of the screen.
18. Virtual Keypad Feature can be used for data entry and value adjustment when the keyboard is not close at hand.

c. Function Screen – Performs system functions. The screen title displays the name of the currently active screen. Use the navigation buttons in the Status Console to change the active function screen.
d. Prompt Line – Displays instructions and feedback needed to perform tasks within the function screen.
e. Process Buttons – Executes operations within the current function screen. These buttons change according to the function screen displayed. The Help button and the Return/Cancel button are always available as process buttons.

B. ANALYZER OPERATION AND MAINTENANCE

1. The VITROS® 4600 is utilized for Stat and Routine testing 24 hours per day and is never placed into a STANDBY mode or turned OFF. Should a power outage occur or troubleshooting requires the analyzer to be powered down, special steps must be taken to shut down and bring the analyzer back to operational status. See Chapter 5 of the VITROS® 4600 Operator's Manual for detailed instructions on System Shutdown and Startup.
2. Daily Maintenance should be performed before QC and patient testing is initiated. From the Status Console touch the Diagnostics button, the Periodic Maintenance button and then the Daily button. The analyzer will provide a list of all activities that need to be completed for Daily Maintenance.
    a. Maintain ERF – Touch the Maintain ERF process button at the bottom of the screen. The analyzer will instruct the operator on how to change and maintain the ERF, including changing and cleaning the reservoir and tip. ERF fluid is changed every 24 hours. A new ERF will be taken from the refrigerator daily, labeled with date, technologist initials and time and left in a designated place to equilibrate. The ERF must be mixed before loading on the analyzer. Follow prompts on the analyzer to complete the maintenance of the ERF.
    b. Perform Metering Maintenance – Touch the Maintain Metering process button at the bottom of the screen. The analyzer will instruct the operator on how to clean the Sample Metering Piston Caps. Follow the prompts on the analyzer to complete maintenance.
    c. Empty Waste Containers
    d. Load Supplies and Remove Empty Outdated Reagents
        I. Touch the Reagents Navigation button at the top of the screen to display all reagents currently loaded on the analyzer.

II. There are 3 supplies of reagents on the analyzer that need to be checked. The Count, Lot#'s, Status, Expiration and Slot # can be viewed for each supply.

III. Expired reagents can be removed by touching the reagent button on the screen and then touching the Load/Unload Process button at the bottom of the screen. The analyzer will indicate when to lift the lid and remove the cartridge. The cartridge will be visible and the green light will be illuminated by the supply door when the cartridge is ready to be removed.

IV. Loading Reagents is done in the same manner as above. Make sure the correct slide supply is selected. Open the foil package, date and initial the reagent cartridge and touch the Load/Unload process button at the bottom of the screen. The analyzer displays on the screen when the cartridge can be loaded. Open the MicroSlide supply cover; the green LED indicators will turn on when the reagent supply door can be opened. Load the cartridge. Cartridges can also be loaded manually by selecting the Manual Load process button. The lot number and open date will be entered into the system and the cartridge can be loaded normally

e. Clean and Inspect the Universal Sample Trays and Adapters.
f. Clean Cap Retainers
g. Clean Versa Tip Supply Registration Rails – Touch Clean V-Tip Rails process button at the bottom of the screen and the analyzer will instruct the operator how to complete the maintenance.

C. Specimen Handling
1. After slides have been loaded into the analyzer, calibrations have been performed and Quality Control had been performed, and is acceptable, the operator programs test selections on a sample-by-sample basis. A maximum of 160 samples can be loaded onto the analyzer at a single time, 150 (15 trays) samples can be accommodated in the Routine sampling lane and 10 samples (1 tray) in the Stat sampling lane. The analyzer is able to download 10,000 sample programs from the LIS.
2. All specimens (blood, CSF, Urine and other body fluids) are centrifuged upon receipt in the laboratory, prior to analysis.
3. If an order is received on a down time requisition or any other temporary requisition, the patient's name, location and collection time must be included. This information gives a record of the specimens received as well as a place to record test results. If an order is received through LIS, the barcode is placed lengthwise on the tube.
4. Specimens to be analyzed are pipetted into sample cups or sampled directly from the uncapped, bar-coded tube. Samples that are pipetted into sample cups should be capped with pierceable sample cup caps.
   a. See Table for recommended cup fill volumes (tests on the VITROS® 4600 have sample volumes of 2ul – 80ul, see the individual package inserts for exact sample volumes required for testing)

Cup/Tube Volume Chart		
Cup Type/Tube Type	**Minimum Fill**	**Maximum Fill**
16X100 (10ml tube)	4500ul + testing volume for Plain Red/Plasma Tubes 0.5 ml + testing volume for SST (gel layer must be at the min. volume level).	18mm from top of tube
16X75 (7ml tube)	450ul + testing volume for Plain Red/Plasma Tubes. 0.5ml + testing volume for SST (gel layer must be at the min. volume level).	18mm from top of tube
13X100	3000ul + testing volume for Plain Red/Plasma Tubes. 0.3 ml + testing volume for SST (gel layer must be at the min. volume level).	18mm from top of tube.
13X75	300ul + testing volume for Plain Red/Plasma Tubes. 0.3ml + testing volume for SST (gel layer must be at the min. volume level).	18mm from top of tube
0.5 ml VITROS Microsample Cup (requires FS MicroSample Cup Adapter in tray)	Test Volume ≤66ul requires 35ul + test volume. Test Volume ≥66ul requires 100ul + test volume.	500ul (Meniscus at cup center is at lower edge of cup rim)
2ml Sample Cup (requires a 16mm tube as an adapter in tray)	100ul + test volume	1500ul (Meniscus at cup center is at lover edge of cup rim)
0.5ml Sample Cup (requires a 16mm tube as an adapter in tray)	100ul + test volume	500ul (Meniscus at cup center is at lower edge of cup rim)
1ml Sample Cup (requires a 13mm tube as an adapter in tray)	100ul + test volume	1ml
B-D MICROTAINER (Requires FS MicroCollection Adapter in tray)	250ul + test volume	Maximum fill volumes as specified by tube manufacturer.

b. Avoid introducing air bubbles into the cup. The minimum fill volume is critical. A low fluid level or bubble stops the metering process and causes one of three error messages:
   1. Insufficient Sample
   2. Drop Error
   3. No Fluid
c. Conversely, for metering reliability, do not overfill cups and avoid getting fluid on the caps.
d. After the cup is filled and capped, it is placed onto one of the sample trays. If analyzing directly from a tube, place it in the sample tray as well.

5. VITROS® programming may be done automatically via a bi-directional interface through the LIS computer system or manually by the operator.
   a. Automatic Programming: LIS automatically downloads all test orders when functioning properly. No operator intervention is necessary. To ensure the barcode is scanned properly, remove the cap and place the tube into the Universal Sample Tray so that it is visible through the slot in the tray. Barcodes must be placed on the tube lengthwise and within 3.2 mm (1/8 in) of the rim of the tube. The barcode must be as perpendicular as possible to the tube's length. Load the tray onto the system and touch the Start Sampling button if sampling is not already in progress.
   b. Manual Programming
      i. Touch the Sample Navigation button at the top of the Status screen to display the Sample Programming Screen.
      ii. Touch the Sample ID Field.
      iii. Type the Sample ID (1-15 alphanumeric characters). The sample ID must be unique. Once all results are complete for a given sample ID or the sample program has been deleted, you can reuse the sample ID.
      iv. Press Enter. The cursor moves to the Tray Field.
      v. Type a tray ID (1 or 2 alphanumeric characters). The tray ID must match the bar code number of the tray used for processing the samples. The system enters the next available cup ID for the tray. To change the cup ID, type another cup position (1-10).
      vi. Press Enter.
      vii. Touch a specimen type. Use the right and left arrows to display more choices.
      viii. Touch the buttons for the tests or panels.
      ix. Touch additional parameters such as auto-dilutions, repetitions or manual dilutions.
      x. Touch Edit Patient Data button at the bottom of screen to add patient demographics.
      xi. Touch Save/Next button at the bottom of the screen.
      xii. Repeat the above steps to program additional samples.
      xiii. Load the tray onto the analyzer and touch the Start Sampling button if sampling is not already in progress.

c. When a tray is loaded on the analyzer, the analyzer will confirm that the tests are calibrated and there are sufficient slides and/or reagents to run the test. If the tests are not calibrated and/or there are insufficient slides to run the test, an alert screen is displayed. The analyzer will automatically attempt to correct any condition that inhibits sample processing with an Auto-Recovery program. If the Auto-Recovery is successful, the system posts a condition code but will continue to process samples, no operator intervention is necessary. If the Auto-Recovery is unsuccessful the system will post a Malfunction-level code requiring operator intervention to continue processing samples.

d. Dilutions are performed manually by the operator when the sample result exceeds the reportable or dynamic range for the assay. See individual analyte SOP's for diluents needed to make manual dilutions.

REPORTING RESULTS

A. Auto-Verified Reporting

1. Auto-verified results that meet a laboratory defined acceptance criteria will be sent directly from the VITROS® into the LIS without any intervention from the technologist.
2. Results that do not meet the predefined acceptance criteria are reviewed by the technologist before being sent to the LIS.

B. On-Line Result Reporting

1. Results are automatically uploaded from the VITROS® into the Sunquest computer. To verify on-line results, answer the Sunquest commands as described below:
    a. FUNCTION: OEM [ENTER]
    b. TECH: [ENTER] to verify tech code
    c. SHIFT: [ENTER] to indicate 1,2 or 3 shift
    d. DEVICE: Site specific INSTRUMENT METHOD CODE, [ENTER]
    e. TEST: [ENTER]
    f. WORKLOAD DATA FOR: [ENTER]
    g. LAST CUP RECEIVED=XXX: LAST CUP PROCESSED=XXX
    h. START AT CUP: Enter 1 number higher than the "Last Cup Processed" if cup number is not shown
    i. CUP XXX ACC. NO._____: If the accession number is correct, press [ENTER]. If not, type in a (**[**) and the correct accession number. **Note: it is essential to include the bracket in order to avoid assigning incorrect results to an accession number.**
    j. Once the correct accession number is entered, pressing [ENTER] will bring up the online results. Carefully compare the results in the computer to those from the VITROS printout. Sunquest will hold up any delta failures or critical results. These must be addressed by the technologist before results can be accepted. If all results match, enter results at the Accept (A), Modify (M), Display Prior (D), Prelim (P) or Reject (R) prompt. If there are any discrepancies reject the results and investigate. After a result is accepted or rejected, the next patient in the online queue will display.

2. Results are automatically uploaded from the VITROS® into the Toplab computer. To verify on-line results, answer the Toplab commands as described below:

a. Pathway: 3,3,1
b. Worklist: Site specific
c. Test Code: Test specific

C. Manual Result Entry

1. The enter results manually; answer the Sunquest commands as described below:
    a. FUNCTION: MEM [ENTER]
    b. TECH: [ENTER] to verify tech code
    c. SHIFT: [ENTER] to indicate 1,2 or 3 shift
    d. WORKSHEET: Site specific Instrument worksheet [ENTER]
    e. DEVICE LAB LOCATION: Verify [ENTER]
    f. TEST-1: [ENTER] FOR ALL TESTS, Type individual test codes for specific tests
    g. More than 50 test requested: defined cap methods will be used
    h. Accept (A) or Modify (M): [ENTER] [ENTER]
    i. ACC. NO.: [ENTER]
    j. Accept (A), Modify (M), Display Prior (D), Prelim (P) or Reject (R): Accept if Correct.
2. The enter results manually; answer the Toplab commands as described below:
    a. Pathway: 3,3,1
    b. Worklist: Site specific
    c. Test Code: Test specific
3. Manually entered results need to be checked and reviewed by a second technologist.

PROCEDURE NOTES

Each patient sample processed will generate a laboratory report with the analyzers results listed. Error codes and flags giving information about the results or possible factors that may have affected the results may be listed on the report. The V-Docs program will give detailed explanations of any code and/or flag.

TROUBLESHOOTING

Consult V-docs (VITROS System Documentation) for any information about the system. V-Docs are the most comprehensive guide to operating, troubleshooting or performing diagnostics available. If the instrument is completely down and the flat panel monitor with touch screen is not able to be accessed, paper manuals are also available but, not as detailed.

REFERENCES

1. Ortho Clinical Diagnostics, VITROS® 5,1 FS Chemistry System Reference Guide, 2014
2. Ortho Clinical Diagnostics, VITROS® V-Docs
3. CHEM.VITROS.1.0 Operation of the 250 and 350 VITROS Analyzer System
4. Ortho Clinical Diagnostics, VITROS® 4600 Chemistry System Training Outline
5. VITROS® Chemistry System Operator Manuals and Reference Guide