CHEM.OPTILITE.1.0 Optilite Operation Manual

PRINCIPLE

The Optilite is a turbidometric photometric instrument designed with 12 filters used to measure absorbance for end point assay measurements and absorbance change per minute for kinetic assay measurements. Within the instrument the cuvette is moved from the cuvette loader into an available slot in the incubator. There are designated positions around the incubator for preparing dilutions, dispensing reagents and samples into the cuvettes, mixing, and for absorbance measurement. The incubator rotates to move the cuvette cells to different positions around the incubator according to the processing steps of each test that is run. After all the cells of one whole cuvette strip are used and measured, the cuvette strip is ejected and discarded to the cuvette waste bin.

OWNERS

Manager, Regional Chemistry & Special Chemistry

RELATED DOCUMENTS

LAB.GEN.QC.1.0

SPECIMEN

- Specific sample requirements for each test can be found in each individual assay procedure.

Refer to package insert guidelines for appropriate sample type, appearance, stability and handling.

- Mix frozen samples prior to testing to insure it is homogenous.
- Inspect samples prior to testing to detect clots or bubbles and remove them
- Check package insert for a list of interferences and guidelines i.e. hemolysis, lipemia

REAGENTS

Optilite analyzer uses only barcoded reagents. The barcode of a system reagent may define lot IDs for quality control and calibrators that are valid for that particular reagent. If these lot IDs of QC and calibrators are defined in the system reagent's barcode, the system test requires that these IDs match each other. However, all the system reagent barcodes do not contain specific calibrator or quality control lot IDs. If a user defined quality control is defined for a system test, this control's lot ID does not need to match reagent's barcode, even though the test would be a lot bound system test.

SUPPLIES REQUIRED

- Appropriate reagent kits from The Binding Site, San Diego, CA 92121
- Optilite Diluent 1 (6x40 ml) - (product no. IK709)
- Optilite Diluent 2 (6x40 ml) - (product no. IK710) check insert for requirement of this product as not required for all kits

- Cuvettes - (product no. IK702)
- 0.5 ml Sample cups (product no. 989220)
- Wash solution 4.5% (100 ml) - (product no.IK704) – Monthly maintenance
- Wash solution 4.5% (20ml) - (product no. IK703) – End Wash
- Tubing Maintenance Solution - (product no. IK705)
- 70% ethanol
- Vikon or broad spectrum disinfectant (option: Thermo Fisher item #3LMC2-10 lbs) or a similar product that does not produce bubbles
- Degassed Di-ionized water (grade 2) (8L water container should ensure approximately 4 hours operation time) Ensure water is degassed for 8 hours (minimum of 4 hours) prior to use.

EQUIPMENT

Refer to Optilite Standard Operation Procedure for details for Equipment, supplies and parts

The analyzer has covers for loading the samples, cuvettes and reagents.

1. Operation buttons
2. Main Power switch
3. Waste container
4. Cuvette waste bin
5. De-gassed Water container
6. Main cover
7. Sample cover
8. Cuvette cover
9. Reagent cover
10. Release Latch

QUALITY CONTROL

A minimum of two levels of controls for all assays except for IG3 and IG4 which require a minimum of three levels spanning the medical decision range are to be run once every 24 hours of assay use. See QC procedure, LAB.GEN.QC.2.0 for specific details.

QC MATERIAL

Refer to department specific QC information
For handing and QC ranges refer to the package insert.

PROCEDURE

Preparing analyzer and workstation

1. Switch on the analyzer from the main switch
2. Switch on the workstation
3. Log on the computer and the program
   User name: Optilite
   Password: Optilie

Note: When the analyzer is switched on, the software checks the content of the sample racks and reagent disk, and updated the user interface according to it.

Note: After switching on the Analyzer, allow 15 minutes for temperature stabilization.

4. Place onboard deionized water that has been degassed overnight
5. Ensure waste container is empty
6. Ensure cuvette waste bin is empty
7. Fill the cuvette loader

Note: Load cuvettes ONLY when indicated by the Optilite Cuvette flags:

Yellow (load 1 package)
Red (load 2 packages)

Starting up

1. Perform the start- up procedure by clinking **Start-up** in the main view

Start-up Note: If Start-up fails the first time, the Optilite will repeat the process. If it fails a second time, the Optilite will return to Start-up Not Complete status and the user needs to initiate a wash step. Two failures will most likely occur due to air in the water lines. Navigate to F5 >Actions and click the Extra Wash button to prime the tubing. Perform this 2-3 times before repeating the Start-up procedure.

The digital maintenance check list will appear following clicking the Start-up button.

Click on **F4 > Maintenance**

Click on **F5 > water blank** results

Inserting reagents

1. Remove the cap from the vial and make sure that there is no air bubbles.
2. Open the reagent cover and insert the reagent into the disk. Make sure that the barcodes on the vials are facing you

- Reagents statuses are color coded to provide information quickly.
  - The following chart shows the status of the reagent:

Indicator		Indication	Description
Blue		OK	The reagent is used normally.
Yellow		Alarm limit	The reagent is below alarm limit.
Red		Short	The reagent is short and it cannot be used for the tests.
Brown		Expired	The reagent is expired or its stability in the analyzer has expired.
Violet		Discarded	The reagent vial cannot be identified. The test must be updated.
Gray		Blocked	The reagent is not in use.
Light blue		Not calibrated	The reagent lot is not calibrated.

Calibrating system tests

1. Select F4> Cal/Ctrl selection> **Calibration**
2. Select a test/tests to check with calibration/controls are needed. Needed calibrators/controls are shown on the right

3. To check if there are system calibrators/controls lots defined for a test which is not in pending status
   a. Select one test
   b. Click **Show req.lots**. The program asks to select correct reagent lot
   c. Select a reagent lot and click OK. Required lots are shown in the *Reg. lot* column. If the *Reg. lot* field is empty, the calibrator/control is not lot bound and whatever lot can be used.
4. Insert calibrator/control vials into the calQC rack. Make sure that the barcodes on the vials are readable from the opening of the rack position
5. Insert the rack into the analyzer
6. Select F4 > CAL/QC selection > **Calibration**
7. Select a test/tests and click **Calibrate**. The program asks to select correct reagents lot.
8. Select a reagent lot to be calibrated and click **OK**.
9. Select F1 > **Start** to perform the requested calibration.

Calibration statuses:

STATUS	DESCRIPTION
Accepted	Calibration curve is accepted.
No calibration	Test has no calibrations.
Expired	A new calibration curve is required.
Pending	Calibration curve is requested.
To be accepted	Calibration curve is required to be accepted.

Performing quality control for system tests

1. Select F4 > Cal/QC selection > **QC**.
2. Select **QC profile**
3. Select a test/tests to check which controls are needed. Needed calibrators/controls and required lots (if they are defined).are shown on the right.
4. Insert control vials into the calQC rack. Make sure that the barcodes on the vials are readable from the opening of the rack position. Lines on bottle and lines on rack need to be aligned perfectly to work.
5. Insert the rack into the analyzer.
6. Select F4 > Cal/QC selection >**QC**.
7. Select **QC Profile**.
8. Select a test/tests and click **Perform QC**.
9. Select F1 > **Start** to perform the requested control.

QC Note: If the QC is out of range the first time, retest the QC ensuring that a bubble or film were not the cause of the failure. If the QC is out of range a second time, recalibrate the assay.

Inserting samples

1. Insert the sample tubes or the cups into the rack. Make sure that the barcodes on the vials are readable from the opening of the rack position.

Note: if non barcoded samples are used, refer to the chapter describing samples

2. Insert the rack into the analyzer.

Analyzing

1. Start the analysis by clicking **Start** in the main view.

Results processing

1. Select F2 > **Reports**.

- The list shows the results and identifications for samples, along with units, status, dilutions and errors

List of Statuses

Statuses
Measured
Calculated (calc.)
Automatically accepted (aut.acc.)
Manually accepted (man.acc.)
Automatically rejected (aut.rej.)
Manually rejected (man.rej.)

- Select the test name, sample ID, patient ID or patient name from the corresponding drop-down menu
- Select the results to be accepted.
- Check for errors before accepting and sending results.
- Review any flags (a chart with handling common flags is below). Check manual for more flag interpretation

Flag	Definition	Action taken by analyser
Dil. limit Low and Outside calibration	Sample measurement is lower than the measuring range for the primary dilution	• Should only be seen at primary dilution • Result displayed as < dilution limit • Samples tested at the primary dilution will auto repeat at the lower dilution
Dil. limit High and Outside calibration	Sample measurement is higher than the measuring range for the dilution	• Seen at primary and higher dilutions • Result displayed as < dilution limit • Samples will auto repeat at the next higher dilution
Test limit High and Outside calibration	The measured concentration is higher than measuring range for the assay	• Seen at highest dilution • Result displayed as > dilution limit • Samples will require manual acceptance or manual rejection
Test limit Low and Outside calibration	The measured concentration is lower than sensitivity for the assay	• Seen at lowest dilution • Results displayed as < dilution limit • Samples will require manual acceptance or manual rejection
Outside calibration	Not expected to be seen. Sample went to a higher dilution but then gave a result below the dilution limit	• Seen at dilutions higher than the primary dilution when the sample is lower than the measuring range • Result displayed as < dilution limit • Samples require manual acceptance or manual rejection

Reporting results

1. Select F2 > **Reports**.
2. Select Samples or Tests from **Select items to report** drop-down menu.
3. Select which results are reported.
4. Print results or create excel report.

Removing reagents

1. Select F3 > **Reagents**
2. Select the vial to be removed.
3. Click **Remove vial**.
4. Remove the vials.

Removing samples, calibrators and controls

1. Select F2 > **Rack disk.**
2. Select the rack to be removed.
3. Click **Remove racks**.
4. Remove the rack.

Clearing daily files

1. Select F5 > **Clear daily files**.

Note: Performing **Clear daily files** operation deletes all results (except control results) if **Sample results archived** parameter in the page F5 > Configuration > **Laboratory** is set **No**.

Note: **Clear daily files** operation cannot be performed if there are results waiting for acceptance

Performing and wash procedure

1. Insert a cup with 2 mL washing solution to the selected samples rack position.
2. Insert the rack into the analyzer.
3. Click **End wash** in the main view.

Switching off analyzer and workstation

Note: Switch off the analyzer only if no reagents are onboard.

1. Select F5 > Actions > **Exit**
2. Switch off the workstation.
3. Switch off the analyzer

Emptying waste container and bin

1. Empty waste water container.
2. Empty cuvette waste bin.

Note: It is recommended to empty the cuvette waste bin after running the daily operations. Furthermore, check the cuvette waste bin before daily routines.

Note: Switching off either the analyzer or the workstation resets the cuvette calculator. Empty and rinse the cuvette waste bin before starting the analyzer or the workstation.

PROCEDURE NOTES

- All operational warnings/flags must be reviewed and accepted by operator.
- To avoid disruption of sample analysis, kit reagents or samples must be added to analyzer within 9 seconds when the Optilite is in operation
- Sort lists by clicking a column heading
- Cuvettes should only be added to analyzer when there is a message/flag to indicate cuvette loading is required. Adding cuvettes prior to instrument prompt may lead to a cuvette jam.
- If Emergency Stop is required, Click STOP in main view to interrupt process immediately.
- Switching off the workstation or removing the cuvette waste bin resets the cuvette waste counter to 0 so verify the waste bin is empty.

REFERENCES

1. Optilite Operation Manual 6.0A in English, The Binding Site, Birmingham England, Document code: INS700.OPT

2. Optilite Reference Manual 6.0A in English, The Binding Site, Birmingham England, Document code INS700.REF