



DXI OV Monitor (CA125)

CHEM.DXI.ASSAY.4.0 DXI OV Monitor (CA125)

PRINCIPLE

The Access OV Monitor assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CA 125 antigen levels in human serum and plasma using the Access Immunoassay Systems. This device is indicated for use in the measurement of CA 125 antigen to aid in the management of ovarian cancer patients. Serial testing for patient CA 125 antigen concentrations should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

The Access OV Monitor assay is a two-site immunoenzymatic (“sandwich”) assay. A sample is added to a reaction vessel along with mouse monoclonal anti-CA 125 antigen alkaline phosphatase conjugate and paramagnetic particles coated with a second mouse monoclonal anti-CA 125 antigen antibody. The CA 125 antigen in the sample binds to the immobilized monoclonal anti-CA 125 antigen on the solid phase, while the conjugate antibody reacts with a different antigenic site on the CA 125 antigen molecule. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of CA 125 antigen in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

OWNERS

Manager, Regional Chemistry

RELATED DOCUMENTS

CHEM.DXI.1.0 DXI Operating Procedure

SPECIMEN

A. Specimen Type

1. Serum
2. Plasma (heparin)

B. Specimen Stability

1. Room Temperature (15-30°C) – 8 hours
2. Refrigerated (2-8°C) – 48 hours
3. Frozen (\leq -20°C) ->48 hours or for shipment

C. Special Instructions

1. Thaw specimens only once.

REAGENTS

A. The reagent is ready to use.

B. Store upright and refrigerate at 2-10°C.

C. Refrigerate at 2-10°C for a minimum of two hours before use on the instrument.



DXI OV Monitor (CA125)

- D. Stable until the expiration date on the label when stored at 2-10°C.
- E. Stable at 2-10°C for 28 days after initial use.
- F. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading onto the instrument.
- G. Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- H. For in vitro diagnostic use.
- I. Handle all reagents with caution and avoid contact with skin, eyes, or mouth. Refer to the Method Manual for any known toxicity.

EQUIPMENT

Beckman Coulter Access UniCel Dxl 600

CALIBRATION

- A. An active calibration curve is required for all tests.
- B. Calibration is required every 28 days for Access OV Monitor.
- C. Calibrators are Ready to Use.
- D. Store upright at 2-10°C.
- E. Mix contents by gently inverting before use
- F. Stable until the expiration date stated on the label when stored at 2-10°C.
- F. Refer to calibration card for exact concentrations.
- G. Refer to the appropriate system manual and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

- A. Refer to CHEM.QC.REGIONAL.2.0 Quality Control Testing Intervals for QC Testing Intervals for appropriate control materials and testing intervals.
- B. Refer to CHEM.QC.REGIONAL.1.0 Regional Chemistry laboratory Quality Control for criteria on accepting/rejecting patients based on control results.
- C. Refer to CHEM.QC.REGCHEM.2.2 QC PREP and STABILITY

PROCEDURE

- A. See, Dxl Operating Procedure, CHEM.DXI.1.0 for specific details.
- B. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

DILUTIONS

- A. for auto or manual dilution refer to CHEM.DXI.1.2 for specific details.

The Dxl system onboard dilution feature automates the dilution process, using predefined assay sample and the Wash Buffer/ Sample Diluent volumes, allowing samples to be quantitated. Results Reported by the system are adjusted for dilution.



DXI OV Monitor (CA125)

REPORTING RESULTS

Refer to, CHEM.DXI.1.1 for Test Codes, AMR, CRR, Critical and Normal Ranges

RESULT ENTRY

A. Sunquest

1. OEM or MEM
2. Worksheet: DXI
3. Method: DXI
4. Test Code: CA125

B. Toplab

1. Enter results in Toplab using Toplab Common Pathway: 3,3,1
2. Toplab Worklist: DXI1
3. Test Code: 29256

C. If HIS or LIS systems are not functional, see the Computer Downtime CHEM.LIS.5.0 procedure.

PROCEDURE NOTES

Use 250 μ L of sample for each determination run with the DXI system.

The Access OV Monitor assay has been evaluated at an ambient temperature range of 18-32°C. For optimal results, assay calibration and patient sample testing should be conducted under similar conditions. If ambient laboratory temperature varies by more than $\pm 5^{\circ}\text{C}$ from the temperature of calibration, review quality control results and recalibrate as necessary

LIMITATIONS

A. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interferes with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples. Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.

B. the Access OV Monitor results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests and other appropriate information. Elevated concentrations may be observed in the serum or plasma of patients with benign conditions or other non-cancer disorders, as well as in ovarian cancer and other metastatic diseases. The Access OV Monitor assay should not be used as a cancer screening test.

REFERENCES

A. Beckman Coulter Access Immunoassay Systems OV Monitor reagent insert (A83832B)