Access
Immunoassay Systems

OV MONITOR
REF 386357

Caution **For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.**

Warning The concentration of CA 125 antigen in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 125 antigen assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining CA 125 antigen values is changed, additional sequential testing should be carried out to confirm baseline values.

Intended Use

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.

Summary and Explanation

The CA 125 antigen is an epitope on a large mucin-like glycoprotein (MW ~ 1000 kDa) [1] that may be found in elevated concentrations in certain ovarian malignancies. There is no known function for CA 125.

Ovarian cancer is one of the most common types of gynecological malignancies, and the fourth most frequent cause of cancer death in women.[2] Ovarian cancer tends to be asymptomatic in its earliest, more curable stages, and many patients have widespread disease at the time of discovery. Some favorable prognostic factors include younger age, lower stage, well-differentiated tumor, and small disease volume prior to surgery.[3]

CA 125 antigen levels have no proven prognostic value when used for either screening or at time of diagnosis. However, CA 125 antigen levels do correlate with patient status after initial treatment.[4,5]

Serum CA 125 antigen levels may be used as an aid in monitoring the response to therapy for patients with epithelial ovarian carcinoma. The presence of persistently rising CA 125 antigen levels may be correlated with disease progression. Persistently elevated CA 125 antigen levels indicate poor response to therapy, whereas decreasing CA 125 antigen levels may indicate a positive therapeutic response.[6,7,8]

CA 125 antigen levels are elevated in many patients with epithelial ovarian carcinoma. It may also be elevated in diseases other than epithelial ovarian carcinoma, including other benign or malignant ovarian diseases, such as endometriosis, and in lung cancer and in other non-cancerous conditions such as pregnancy.

Historically, CA 125 antigen levels have been used in conjunction with second-look surgery, but this procedure is less commonly used today.[8,9] A recent NIH Consensus panel has recommended the use of serial CA 125 testing in lieu of second look surgery, at least for those women with a preoperative increase of CA 125.[10,11]

The Access OV Monitor assay is not recommended as a screening tool. A value below the cutoff limit does not indicate the absence of residual ovarian cancer. Other clinically acceptable tests and procedures should also be considered in the monitoring of ovarian cancer and good patient management.

Some individuals have antibodies to mouse protein (HAMA) which can cause interference in immunoassays that employ antibodies derived from mice. In particular, it has been reported that serum samples from patients who have undergone therapeutic or diagnostic procedures that include infusion of mouse monoclonal antibodies may produce erroneous results in such assays. Additionally, other heterophile antibodies may be present in patient samples. Therefore, results for such patients should be used only in conjunction with results from some other diagnostic procedures and with information available from the clinical evaluation of the patient.

Principles of the Procedure

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.

Product Information

Access OV Monitor Reagent Pack

Cat. No. 386357: 100 determinations, 2 packs, 50 tests/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 28 days after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the reagent pack is damaged (i.e., broken elastomer), discard the pack.
- All antisera are polyclonal unless otherwise indicated.

R1a:	Paramagnetic particles, coated with goat anti-biotin antibodies, biotinylated anti CA 125 antigen mouse monoclonal antibodies, bovine serum albumin, < 0.1% sodium azide and 0.1% ProClin** 300.
R1b:	Mouse monoclonal anti-CA 125 antigen-alkaline phosphatase (bovine) conjugate, bovine serum albumin, < 0.1% sodium azide and 0.1% ProClin 300.
R1c:	Buffered protein solution (bovine, goat, mouse), < 0.1% sodum azide and 0.1% ProClin 300.

Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination.

Store and dispose of these materials and their containers in accordance with local regulations and guidelines.

- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[12]
- Xi. Irritant: 0.1% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

Specimen Collection and Preparation

1. Serum and plasma (heparin) are the recommended samples.
2. Observe the following recommendations for handling, processing, and storing blood samples: [13]
   - Collect all blood samples observing routine precautions for venipuncture.
   - Allow serum samples to clot completely before centrifugation.
   - Keep tubes stoppered at all times.
   - Within two hours after centrifugation, transfer at least 500 µL of cell-free sample to a storage tube. Tightly stopper the tube immediately.
   - Store samples tightly stoppered at room temperature (15 to 30°C) for no longer than eight hours.
   - If the assay will not be completed within eight hours, refrigerate the samples at 2 to 8°C.
   - If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20°C or colder.
   - Thaw samples only once.
3. Use the following guidelines when preparing specimens:
   - Ensure residual fibrin and cellular matter has been removed prior to analysis.
   - Follow blood collection tube manufacturer's recommendations for centrifugation.
4. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.

Materials Provided

R1 Access OV Monitor Reagent Packs

Materials Required But Not Provided

1. Access OV Monitor Calibrators
   Provided at zero and approximately 25, 100, 500, 2,000 and 5,000 U/mL.
   Cat. No. 386358
2. Quality Control (QC) materials: commercial control material
3. Access Sample Diluent A
   Vial Cat. No. 81908
   Diluent Pack Cat. No. A79783 (For use with the UniCel DxI system onboard dilution feature.)
4. Access Substrate
   Cat. No. 81906
5. **Access, Access 2, SYNCHRON LXi:**
   Access Wash Buffer II, Cat. No. A16792
   UniCel DxI:
   UniCel DxI Wash Buffer II, Cat. No. A16793

Procedural Comments

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use twenty-five (25) µL of sample for each determination in addition to the sample container and system dead volumes. Use twenty-five (25) µL of sample in addition to the sample container and system dead volumes for each determination run with the DxI system onboard dilution feature. Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. The system default unit of measure for sample results is U/mL.

Procedure

Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

Calibration Details

An active calibration curve is required for all tests. For the Access OV Monitor assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

Quality Control

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.[14] Include commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

Results

Patient test results are determined automatically by the system software using a weighted four parameter logistic curve (4PLC) math model. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. Patient test results can be reviewed using the appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

Limitations of the Procedure

1. Samples can be accurately measured within the analytic range of the lower limit of detection and the highest calibrator value (approximately 0.5 U/mL and 5,000 U/mL).
   - If a sample contains less than the lower limit of detection for the assay, report the results as less than that value (i.e., < 0.5 U/mL). When the DxI system onboard dilution feature is used, the system will report results as less than 4,250 U/mL.
   - If a sample contains more than the stated value of the highest Access OV Monitor Calibrator (S5), report the result as greater than that value (i.e., > 5,000 U/mL). Alternatively, dilute one volume of sample with 9 or 19 volumes of Access OV Monitor Calibrator S0 (zero) or Access Sample Diluent A. Refer to the appropriate system manuals and/or Help system for instructions on entering a sample dilution in a test request. The system reports the results adjusted for the dilution.
     The DxI system onboard dilution feature automates the dilution process, using one volume of sample with nineteen volumes of Access Sample Diluent A, allowing samples

to be quantitated up to approximately 100,000 U/mL. The system reports the results adjusted for the dilution.

2. 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 have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce antibodies, e.g. HAMA, that interfere with immunoassays. Additionally, other heterophile antibodies such as human anti-goat antibodies may be present in patient samples.[15,16]
   Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.
3. 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. Serum or plasma OV Monitor concentrations should not be interpreted as absolute evidence for the presence or absence of cancer. 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.
4. The Access OV Monitor assay does not demonstrate any "hook" effect up to 120,000 U/mL.

Expected Values

1. Each laboratory should establish its own reference ranges to assure proper representation of specific populations.
2. The distribution of Access OV Monitor results, presented below, were determined from a total of 889 serum samples from apparently healthy females and males and females with non-malignant and malignant conditions.

Subject Category	Number of Subjects	0–35 U/mL	35.1–65 U/mL	65.1–100 U/mL	> 100 U/mL
Apparently Healthy					
Females	170	166	3	1	0
Males	51	51	0	0	0
Malignant Conditions (including previously treated patients)					
Ovarian	141	94	10	6	31
Breast	48	43	3	1	1
Cervical	27	22	1	1	3
Colon	50	47	2	1	0
Endometrial	8	5	2	1	0
Esophageal	9	7	1	0	1
Fallopian Tube	5	3	0	1	1
Gastric/Stomach	13	7	2	2	2
Lung	50	28	9	3	10
Pancreatic	25	14	0	2	9
Uterine	26	19	1	1	5
Vaginal/Vulva	12	11	1	0	0
Non-Malignant Conditions (including previously treated patients)					
Ovarian	28	28	0	0	0
Colon	43	43	0	0	0
Cystitis	9	8	1	0	0
Endometriosis	22	21	0	1	0
Gastric/Stomach	39	37	1	0	1
Pelvic Inflammatory Disease	8	7	1	0	0
Uterine Fibroids	30	25	1	1	3
Pregnancy	75	42	22	4	7

Clinical Performance in Ovarian Cancer Patients

Relative Sensitivity and Specificity

Relative sensitivity and specificity were calculated for the Access OV Monitor vs. another automated commericially available assay. In this study sensitivity and specificity calculations were based on the 35 U/mL upper reference limit for both assays. The analyses are based on 141 samples from 141 subjects originally diagnosed with ovarian cancer (stages I to IV) and at various stages of the disease. These subjects may have undergone surgery, chemotherapy, or radiation during the course of disease management. A non-parametric Wilcoxon analysis of results demonstrate that the median CA 125 values are not statistically different between the Access OV Monitor assay and the reference CA 125 assay with p-value = 0.9557. Based on the 141 ovarian cancer subjects, the relative sensitivity and specificity were 95.8% and 98.9%, respectively.

Clinical Concordance (Sensitivity and Specificity)

In this study, clinical sensitivity and specificity were based on the 35 U/mL upper reference limit. Clinical sensitivity is calculated based on a total of 45 serum samples from 45 females originally diagnosed with ovarian cancer (stage II to stage IV) and who are diagnosed with disease progression at the time of sample draw date. Clinical specificity calculations are based on a total of 63 samples from 63 females originally diagnosed with ovarian cancer (stage II to stage IV) and who are diagnosed with no evidence of disease (NED) at the time of sample draw date. These subjects may have undergone surgery, chemotherapy, or radiation during the course of disease management. Based on these two populations, the clinical sensitivity and specificity, based on the 35 U/mL upper reference limit, were 84.4% and 82.5%, respectively. Disease status is based on one or more clinical diagnostic modalities. The method(s) used to determine disease status at sample draw date included: biopsy, physical exam, x-rays, exploratory laparoscopy, CAT scan, ultrasound, pelvic echogram, isotope scan, CA 125 measurements, MRI.

In addition to the above studies, serial samples with known disease status (total of 118 samples) were obtained from 20 females (ages ranging from 27 to 84 years) who were diagnosed with ovarian cancer (stages I to IV ovarian cancer). These subjects were monitored over the course of disease, ranging from 7 months to 53 months. Presented below is a summary table showing the concordance of clinical results relative to the 35 U/mL cut-off using the Access OV Monitor assay.

Access OV Monitor Serial Evaluation – # of Observations (20 Patients/118 Total Samples)		
Disease status at time of sample draw	**Access OV Monitor**	
	< 35 U/mL	**≥ 35 U/mL**
Progression*	8	41
Completed Remission**	36	7
Partial Remission	6	10
Minimal Improvement	3	7
Concordance: Progression (Clinical Sensitivity)	41/49 (83.7%)	
Concordance: Response to therapy (NED)* (Clinical Specificity)**	36/43 (83.7%)	

* Used for the Clinical Sensitivity Calculation
** Used for the Clinical Specificity Calculation
*** No evidence of disease (NED)

Of the 118 samples with known disease status information, 49 samples were classified as progression (or active disease), 43 samples as complete remission (NED), 16 samples as partial remission, and 10 samples as minimal improvement. The clinical sensitivity (based on the 49 progression samples) and the clinical specificity (based on the 43 complete remission samples) were 83.7% and 83.7%, respectively. For this ovarian cancer population, identical clinical

sensitivity and clinical specificity results were obtained between the Access OV Monitor assay and the commercially available automated assay discussed in the Relative Sensitivity and Specificity section above.

Specific Performance Characteristics

Methods Comparison

A comparison of 290 values using the Access OV Monitor assay on the Access Immunoassay system and a commercially available immunoassay system gave the following statistical data using Deming calculations:

n	Range of Observations (U/mL)	Intercept (U/mL)	Slope	Correlation Coefficient (r)
290	0–600	-1.0	1.20	0.9871

Dilution Recovery (Linearity)

Multiple dilutions of 3 samples containing various CA 125 antigen levels with Access OV Monitor Calibrator S0 (zero) resulted in the following data:

Sample 1 (ID)	Dilution (U/mL)	Expected Concentration (U/mL)	Determined Concentration (U/mL)	Recovery (%)
A	0	2659	2659	100
	1:2	1329	1334	100.4
	1:5	532	560	105.3
	1:10	266	291	109.4
	1:100	27	30	111.1
			Mean % Recovery	**107**

Sample 2 (ID)	Dilution (U/mL)	Expected Concentration (U/mL)	Determined Concentration (U/mL)	Recovery (%)
B	0	4277	4277	100
	1:2	2139	2211	103.4
	1:5	855	938	109.7
	1:10	428	460	107.5
	1:200	21	24	114.3
			Mean % Recovery	**109**

Sample 3 (ID)	Dilution (U/mL)	Expected Concentration (U/mL)	Determined Concentration (U/mL)	Recovery (%)
C	0	2186	2186	100
	1:2	1093	1131	103.5
	1:5	437	490	112.1
	1:10	219	248	113.5
	1:100	22	24	109.1
			Mean % Recovery	**109**

Imprecision

This assay exhibits total imprecision of less than 10% across the assay range. One study, using commercially available human serum based control material generating a total of 20 assays, 2

replicates per assay, over 10 days provided the following data, analyzed via analysis of variance (ANOVA).

Sample	Grand Mean (n=43) (U/mL)	Within Run (%CV)	Between Run (%CV)	Total Imprecision (%CV)
Level 1	23.6	1.7	6.0	6.3
Level 2	74.7	1.3	5.1	5.3
Level 3	740.9	2.1	4.4	4.8
Level 4	2961.8	2.4	3.3	4.1

Analytical Specificity / Interferences

Samples containing up to 1000 mg/dL hemoglobin, 20 mg/dL bilirubin, 1800 mg/dL triglycerides (triolein) and protein concentrations from 5.0 to 9.0 g/dL protein (human serum albumin) do not affect the concentration of CA 125 antigen assayed.

The following table describes the cross-reactivity of the assay with common chemotherapeutic agents and other potential interferents.

Substance	Concentration Added	Expected (U/mL)	Observed (U/mL)	Mean % Recovery
Doxorubicin	100 µg/mL	15.0	15.4	102.7
Amethopterin	500 µg/mL	15.0	14.9	99.3
Carboplatin	1,000 µg/mL	15.0	15.2	101.3
Cyclophosphamide	1,000 µg/mL	15.0	14.6	97.3
5-fluorouracil	1,000 µg/mL	15.0	14.8	98.7
Cisplatin	2,000 µg/mL	15.0	14.7	98.0
Melphalan	100 µg/mL	15.0	14.6	97.3
Acetominophen	200 µg/mL	15.0	15.2	101.3
Aspirin	500 µg/mL	15.0	15.0	100.0
Paclitaxel	10 ng/mL	15.0	15.1	100.7
Biotin	50 ng/mL	15.0	14.4	96.0
Vitamin D_2	1 U/mL	15.0	14.9	99.3

Analytical Sensitivity

The lowest detectable level of CA 125 antigen distinguishable from zero (Access OV Monitor Calibrator S0) with 95% confidence is 0.5 U/mL. This value is determined by processing a complete six point calibration curve, controls, and 10 replicates of the zero calibrator in multiple assays. The analytical sensitivity value is calculated from the curve at the point that is two standard deviations from the fitted zero calibrator signal.

Access
Immunoassay Systems

OV MONITOR CALIBRATORS
REF 386358

Caution **For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.**

Warning The concentration of CA 125 antigen in a given specimen determined with assays from different manufacturers can vary due to differences in assay methods and reagent specificity. The results reported by the laboratory to the physician must include the identity of the CA 125 antigen assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of monitoring a patient, the assay method used for determining CA 125 antigen values is changed, additional sequential testing should be carried out to confirm baseline values.

Intended Use

The Access OV Monitor Calibrators are intended to calibrate the Access OV Monitor assay for the quantitative determination of CA 125 antigen levels in human serum and plasma using the Access Immunoassay Systems.

Summary and Explanation

Quantitative assay calibration is the process by which samples with known analyte concentrations (i.e., assay calibrators) are tested like patient samples to measure the response. The mathematical relationship between the measured responses and the known analyte concentrations establishes the calibration curve. This mathematical relationship, or calibration curve, is used to convert RLU (Relative Light Unit) measurements of patient samples to specific quantitative analyte concentrations.

Traceability

The measurand (analyte) in the Access OV Monitor Calibrators is traceable to the manufacturer's working calibrators. Traceability process is based on EN ISO 17511.

The assigned values were established using representative samples from this lot of calibrator and are specific to the assay methodologies of the Access reagents. Values assigned by other methodologies may be different. Such differences, if present, may be caused by inter-method bias.

Product Information

Access OV Monitor Calibrators

Cat. No. 386358: S0–S5, 2.5 mL/vial

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Signs of possible deterioration are control values out of range.
- Refer to calibration card for exact concentrations.

S0:	Buffered bovine serum albumin (BSA), < 0.1% sodium azide and 0.5% ProClin** 300.
S1, S2, S3, S4, S5:	CA 125 antigen at levels of approximately 25, 100, 500, 2000 and 5000 U/mL, in buffered BSA, < 0.1% sodium azide and 0.5% ProClin 300.
Calibration Card:	1

Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Human source material used in the preparation of the reagent has been tested and found negative or non-reactive for Hepatitis B, Hepatitis C (HCV), and Human Immunodeficiency Virus (HIV-1 and HIV-2). Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.[17]
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[12]
- Xi. Irritant: 0.5% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

Procedure

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

Calibration Details

The Access OV Monitor is reported in U/mL. Assay calibration data are valid up to 28 days.

Calibrators run in duplicate.

Limitations of the Procedure

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

Access
Immunoassay Systems

SAMPLE DILUENT A

REF 81908 (Vial)

REF A79783 (Diluent Pack)

Intended Use

The Access Sample Diluent A is intended for use with Access assays to dilute patient samples containing analyte concentrations greater than the analyte specific S5 calibrator.

Summary and Explanation

The analyte level in patient samples may exceed the level of the specific S5 calibrator. If a quantitative value is required, it will be necessary to dilute the samples in order to determine the analyte concentration.

Product Information

Access Sample Diluent A

Cat. No. 81908: 4 mL/vial

- Provided ready to use.
- Allow the contents to stand for 10 minutes at room temperature.
- Mix gently by inverting before use. Avoid bubble formation.
- Stable until the expiration date stated on the vial label when stored at 2 to 10°C.

Diluent	Buffered BSA matrix with surfactant, < 0.1% sodium azide, 0.5% ProClin** 300.

Cat. No. A79783: 2 diluent packs, 32.9 mL/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 56 days after initial use of each well.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the diluent pack is damaged (i.e., broken elastomer), discard the pack.

R1a – R1e:	Buffered BSA matrix with surfactant, < 0.1% sodium azide, 0.5% ProClin 300.

Warnings and Precautions

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.[12]

- Xi. Irritant: 0.5% ProClin 300.

R 43: May cause sensitization by skin contact.
S 28-37: After contact with skin, wash immediately with plenty of soap and water. Wear suitable gloves.

- The Material Safety Data Sheet (MSDS) is available upon request.

Procedure

Samples can be accurately measured within the analytic range of the lower limit of detection and the highest calibrator value of the specific assay. If a sample contains more analyte than the stated value of the S5 calibrator, dilute the sample following dilution instructions in the specific assay labeling under "Limitations of Procedure" in the reagent pack section. Refer to the appropriate system manuals and/or Help system for instructions on how to enter a sample dilution in a test request.

Limitations of the Procedure

If there is evidence of microbial contamination or excessive turbidity in the reagent, discard the vial.

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