Monobind Inc.®
Lake Forest, CA 92630, USA

AccuLite®
CLIA Microwells

Cancer Antigen 15-3 (CA 15-3)
AccuLite® CLIA Test System
Product Code: 5675-300

1.0 INTRODUCTION

Intended Use: The Quantitative Determination of Cancer Antigen 15-3 (CA 15-3) Concentration in Human Serum by a Microplate Enzyme Immunoassay, Chemiluminescence

2.0 SUMMARY AND EXPLANATION OF THE TEST

Although multiple serum based tumor markers have been described for breast cancer, such as CA 15-3, BR 27-29, carcinoembryonic antigen (CEA), tissue polypeptide antigen (TPA), tissue polypeptide specific antigen, and HER-2 (the extracellular domain), the most widely used are CA 15-3 and CEA. CA 15-3 is considered to be one of the first circulating prognostic factors for breast cancer.[1] Preoperative concentrations thus might be combined with prognostic factors for predicting outcome in patients with newly diagnosed breast cancer.[2] At present, the most important clinical application of CA 15-3 is in monitoring therapy in patients with advanced breast cancer that is not accessible by existing clinical or radiologic procedures.[3]

The CA 15-3 assay measures the protein product of *MUC1* gene. *MUC1* protein is a large transmembrane glycosylated molecule containing three main domains, a large extracellular region, a membrane spanning sequence, and a cytoplasmic domain.[4] Although the physiologic function of *MUC1* is unclear, the glycoprotein has been implicated in cell adhesion, immunity and metastasis. Compared with healthy breast tissue, *MUC1* is present in higher concentrations, but less glycosylated in breast carcinoma.[5-8]

In this method, a pre-diluted CA15-3 calibrator diluted patient specimen or control is first added to a streptavidin coated well. Biotinylated monoclonal antibody (specific for CA15-3) is added and the reactants mixed. Reaction between the CA15-3 antibodies and native CA15-3 forms complex that binds with the streptavidin coated to the well. The excess serum proteins are washed away via a wash step. Another enzyme labeled antibody specific for a different epitopic recognition of CA15-3 is added to the wells. The enzyme labeled antibody binds to the CA15-3 already immobilized on the well through its binding with the biotinylated monoclonal antibody. Excess enzyme is washed off via a wash step. Light is generated by the addition of a substrate. The intensity of the light generation is directly proportional to the concentration of the CA15-3 in the sample.

3.0 PRINCIPLE

Immunoenzymometric sequential assay (TYPE 4):
The essential reagents required for an immunoenzymometric assay include high affinity and specificity antibodies (enzyme and immobilized), with different and distinct epitope recognition, **in excess,** and native antigen. In this procedure, the immobilization takes place during the assay at the surface of a microplate well through the interaction of streptavidin coated on the well and exogenously added biotinylated monoclonal anti-CA15-3 antibody.

Upon mixing monoclonal biotinylated antibody, and a serum containing the native antigen, reaction results between the native antigen and the antibody, forming an antibody-antigen complex. The interaction is illustrated by the following equation:

$$Ag_{(CA15\text{-}3)} + {}^{Btn}Ab_{(m)} \underset{k_{-a}}{\overset{k_a}{\rightleftharpoons}} Ag_{(CA15\text{-}3)} - {}^{Btn}Ab_{(m)}$$

$^{Btn}Ab_{(m)}$ = Biotinylated Monoclonal Antibody (Excess Quantity)
$Ag_{(CA15\text{-}3)}$ = Native Antigen (Variable Quantity)
$Ag_{(CA15\text{-}3)} - {}^{Btn}Ab_{(m)}$ = Antigen-antibody complex (Variable Quantity)
k_a = Rate Constant of Association
k_{-a} = Rate Constant of Disassociation

Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin and biotinylated antibody. This interaction is illustrated below:
$Ag_{(CA15\text{-}3)} - {}^{Btn}Ab_{(m)} + Streptavidin_{CW} \Rightarrow$ Immobilized complex (IC)
$Streptavidin_{CW}$ = Streptavidin immobilized on well
Immobilized complex (IC) = Ag-Ab bound to the well

After a suitable incubation period, the antibody-antigen bound fraction is separated from unbound antigen by decantation or aspiration. Another antibody (directed at a different epitope) labeled with an enzyme is added. Another interaction occurs to form an enzyme labeled antibody-antigen-biotinylated-antibody complex on the surface of the wells. Excess enzyme is washed off via a wash step. A suitable substrate is added to produce color measurable with the use of a microplate spectrophotometer. The enzyme activity, determined by reaction with a substrate (luminol) that generates light, in the antibody-bound fraction is directly proportional to the native antigen concentration. By utilizing several different serum references of known antigen concentration, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

$$(IC) + {}^{Enz}Ab_{(x\text{-}CA15\text{-}3)} \underset{k_{-b}}{\overset{k_b}{\rightleftharpoons}} {}^{Enz}Ab_{(x\text{-}CA15\text{-}3)} - IC$$

$^{Enz}Ab_{(x\text{-}CA15\text{-}3)}$ = Enzyme labeled Antibody (Excess Quantity)
$^{Enz}Ab_{(x\text{-}CA15\text{-}3)}$ - IC = Antigen-Antibodies Complex
k_b = Rate Constant of Association
k_{-b} = Rate Constant of Dissociation

4.0 REAGENTS

Materials Provided:

A. CA 15-3 Calibrators – 1.0 ml/vial - Icons A-F
Six (6) vials of serum reference calibrators at concentrations of 0 (**A**), 10 (**B**), 40 (**C**), 100 (**D**), 200 (**E**) and 400 (**F**) U/ml. A preservative has been added. Store at 2-8°C.
Note 1: The calibrators are provided prediluted.
Note 2: The calibrators, human serum based, were made using a purified preparation of CA 15-3. The preparation was calibrated against Centocor CA 15-3 IRMA test.

B. CA15-3 Biotin Reagent – 12 ml/vial – Icon ∇
One (1) vial contains biotinylated anti-human CA15-3 mIgG in a protein-stabilized matrix. A preservative has been added. Store at 2-8°C.

C. CA15-3 Tracer Reagent – 12 ml/vial - Icon
One (1) vial contains horseradish peroxidase incorporated anti-human CA15-3 mIgG in a protein-stabilized matrix. A preservative has been added. Store at 2-8°C.

D. Light Reaction Wells – 96 wells – Icon ⇓
One 96-well microplate coated with streptavidin and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

E. Wash Solution Concentrate – 20ml/vial - Icon
One (1) vial contains surfactant in buffered saline. A preservative has been added. Store at 2-8°C.

F. CA 15-3 Dilution Matrix – 50 ml/vial – No Icon
One (1) vial contains buffer salts, protein, and surfactants. Store at 2-8°C.

G. Signal Reagent A – 7ml/vial - Icon C^A
One (1) vial contains luminol in buffer. Store at 2-8°C (see Reagent Preparation Section).

H. Signal Reagent B – 7ml/vial - Icon C^B
One (1) vial contains hydrogen peroxide (H_2O_2) in buffer. Store at 2-8°C (see Reagent Preparation Section).

I. Product Insert.

Note 1: Do not use reagents beyond the kit expiration date.

Note 2: Avoid extended exposure to heat and light. **Opened reagents are stable for sixty (60) days when stored at 2-8°C. Kit and component stability are identified on the label.**
Note 3: Above reagents are for a single 96-well microplate**.**

4.1 Required But Not Provided:
1. Pipette capable of delivering 0.25ml (25µl) and 100ml (100µl) with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100ml (100µl) and 0.350ml (350µl) volumes with a precision of better than 1.5%.
3. Pipette (1000µl) used for serum diluent in patient dilutions.
4. Microplate washer or a squeeze bottle (optional).
5. Microplate luminometer.
6. Absorbent Paper for blotting the microplate wells.
7. Plastic wrap or microplate cover for incubation steps.
8. Vacuum aspirator (optional) for wash steps.
9. Timer.
10. Quality control materials.

5.0 PRECAUTIONS

For In Vitro Diagnostic Use
Not for Internal or External Use in Humans or Animals

All products that contain human serum have been found to be non-reactive for Hepatitis B Surface Antigen, HIV 1&2 and HCV Antibodies by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS Publication No. (CDC) 88-8395.

Safe disposal of kit components must be according to local regulatory and statutory requirement.

6.0 SPECIMEN COLLECTION AND PREPARATION:

The specimens shall be blood serum or heparanised plasma in type and taken with the usual precautions in the collection of venipuncture samples. For accurate comparison to establish normal values, a fasting morning serum sample should be obtained. The blood should be collected in a redtop (with or without gel additives) venipuncture tube or for plasma use evacuated tube(s) containing heparin. Allow the blood to clot for serum samples. Centrifuge the specimen to separate the serum or plasma from the cells.

In patients receiving therapy with high biotin doses (i.e. >5mg/day), no sample should be taken until at least 8 hours after the last biotin administration, preferably overnight to ensure fasting sample.

Samples may be refrigerated at 2-8ºC for a maximum period of five (5) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20ºC for up to 30 days. Avoid use of contaminated devices. Avoid repetitive freezing and thawing. When assayed in duplicate, 0.050ml (50µl) of the diluted specimen is required.

7.0 QUALITY CONTROL

Each laboratory should assay controls at levels in the low, normal and elevated range for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

8.0 REAGENT PREPARATION:

1. Wash Buffer
Dilute contents of wash solution to 1000ml with distilled or deionized water in a suitable storage container. Diluted buffer can be stored at room 2-30°C for up to 60 days.

2. Working Signal Reagent Solution - Store at 2 - 8°C.
Determine the amount of reagent needed and prepare by mixing equal portions of Signal Reagent A and Signal Reagent B in a clean container. For example, add 1 ml of A and 1ml of B per two (2) eight well strips (a slight excess of solution is made). **Discard the unused portion if not used within 36 hours after mixing.** If complete utilization of the reagents is anticipated, within the above time constraint, pour the contents of Signal Reagent B into Signal Reagent A and label accordingly.

3. Patient Sample Dilution (1:21)
Dispense 0.025ml (25µl) of each control and/or patient specimen into 0.500ml (500µl) of CA 15-3 dilution matrix appropriately labeled, clean container(s) and mix thoroughly before use. Store refrigerated at 2-8°C for up to 48 hours.

Note: Do not use reagents that are contaminated or have bacteria growth.

9.0 TEST PROCEDURE

Before proceeding with the assay, bring all reagents, serum reference calibrators and controls to room temperature (20-27°C).
*****Test procedure should be performed by a skilled individual or trained professional*****

1. Format the microplates' wells for each serum reference calibrator, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8ºC.**
2. Pipette 0.025ml (25µl) of the appropriate diluted serum reference calibrator, control or specimen into the assigned well.
3. Add 0.100ml (100µl) of the biotinylated labeled antibody to each well. **It is very important to dispense all reagents close to the bottom of the coated well.**
4. Swirl the microplate gently for 20-30 seconds to mix and cover.
5. Incubate 45 minutes at room temperature.
6. Discard the contents of the microplate by decantation or aspiration. If decanting, tap and blot the plate dry with absorbent paper.
7. Add 0.350ml (350µl) of wash buffer (see Reagent Preparation Section), decant (tap and blot) or aspirate. Repeat four (4) additional times for a total of five (5) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat four (4) additional times.**
8. Add 0.100ml (100µl) of the CA15-3 Tracer Reagent to each well.
DO NOT SHAKE THE PLATE AFTER TRACER ADDITION
9. Cover and incubate 45 minutes at room temperature.
10. Discard the contents of the microplate by decantation or aspiration. If decanting, blot the plate dry with absorbent paper.
11. Add 0.350ml (350µl) of wash buffer (see Reagent Preparation Section), decant (tap and blot) or aspirate. Repeat four (4) additional times for a total of five (5) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is employed, fill each well by depressing the container (avoiding air bubbles) to dispense the wash. Decant the wash and repeat four (4) additonal times.**
12. Add 0.100 ml (100µl) of working signal reagent to all wells (see Reagent Preparation Section).). **Always add reagents in the same order to minimize reaction time differences between wells.**
DO NOT SHAKE PLATE AFTER SIGNAL ADDITION
13. Incubate for five (5) minutes in the dark.
14. Read the Relative Light Units (RLUs) in each well for 0.2 – 1.0 seconds. **The results should be read within thirty (30) minutes of adding the signal solution.**

10.0 CALCULATION OF RESULTS

A dose response curve is used to ascertain the concentration of CA15-3 in unknown specimens.
1. Record the RLUs obtained from the printout of the luminometer as outlined in Example 1.
2. Plot the RLUs for each duplicate serum reference versus the corresponding CA 15-3 concentration in U/ml on linear graph paper (do not average the duplicates of the serum references before plotting).
3. Connect the points with a best-fit curve.
4. To determine the concentration of CA 15-3 for an unknown, locate the average RLU of the duplicates for each unknown on

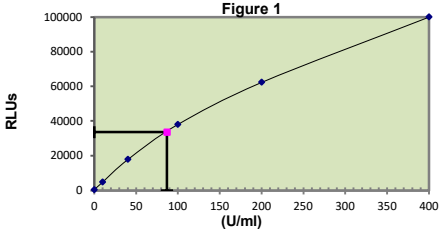
the vertical axis of the graph, find the intersecting point on the curve, and read the concentration (in U/ml) from the horizontal axis of the graph (the duplicates of the unknown may be averaged as indicated). In the following example, the RLUs (33622) intersects the dose response curve at (86.7U/ml) CA 15-3 concentration (See Figure 1).

Note: Computer data reduction software designed for CLIA assay may also be used for the data reduction. If such software is utilized, the validation of the software should be ascertained.

EXAMPLE 1

Sample I.D.	Well Number	RLUs (A)	Mean RLU (B)	Value (U/ml)
Cal A	A1	452	462	0
	B1	472		
Cal B	C1	4936	4920	10
	D1	4905		
Cal C	E1	17471	17886	40
	F1	18301		
Cal D	G1	37475	38072	100
	H1	38669		
Cal E	A2	61173	62300	200
	B2	63427		
Cal F	C2	103731	100000	400
	D2	96269		
Patient	E2	33142	33622	**86.7**
	F2	34102		

Figure 1



* The data presented in Example 1 and Figure 1 is for illustration only and **should not** be used in lieu of a dose response curve prepared with each assay. In addition, the RLUs of the calibrators have been normalized to 100,000 RLUs for the A calibrator (greatest light output). This conversion minimizes differences caused by efficiency of the various instruments that can be used to measure light output.

11.0 Q.C. PARAMETERS

In order for the assay results to be considered valid the following criteria should be met:

1. The Dose Response Curve should be within established parameters.
2. If used, 2 of 3 quality control pools should be within the established range.

12.0 RISK ANALYSIS

The SDS is available at https://www.monobind.com/safety-data-sheets and the Risk Analysis Form may be requested.

12.1 Assay Performance

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the dose response curve.
5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.
6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
7. Use components from the same lot. No intermixing of reagents from different batches.
8. Patient specimens (diluted) with CA 15-3 concentrations above 400 U/ml may be further diluted (1/10 or higher) with CA15-3 diluted serum diluent and re-assayed. The sample's concentration is obtained by multiplying the result by the dilution factor.
9. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed are essential. Any deviation from Monobind IFU may yield inaccurate results.
10. All applicable national standards, regulations and laws, including, but not limited to, good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
11. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and/or the automated instruments used with this device, and to perform routine preventative maintenance.
12. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from Monobind@monobind.com.

12.2 Interpretation

1. ***Measurements and interpretation of results must be performed by a skilled individual or trained professional.***
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. The reagents for AccuLite® CLIA procedure have been formulated to eliminate maximal interference; however, potential interaction between rare serum specimens and test reagents can cause erroneous results. Heterophilic antibodies often cause these interactions and have been known to be problems for all kinds of immunoassays. (Boscato, LM, Stuart, MC. "Heterophilic antibodies: a problem for all immunoassays'' *Clin. Chem*. 1988:3427-33). For diagnostic purposes, the results from this assay should be used in combination with clinical examination, patient history and all other clinical findings.
4. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
5. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
6. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.
7. CA 15-3 has a low clinical sensitivity and specificity as a tumor marker. Clinically an elevated CA 15-3 value alone is not of diagnostic value as a test for cancer and should only be used in conjunction with other clinical manifestations (observations) and diagnostic parameters.

13.0 EXPECTED RANGES OF VALUES:

The serum CA 15-3 is elevated in 2% of normal healthy women and 7% of patients with non-neoplastic conditions. Also, it has been reported to be elevated in cases of liver, lung, ovarian and colorectal cancers. No definitive ranges have been reported for those conditions.

TABLE I
Expected Values for the CA 15-3 AccuLite® CLIA Test System

Healthy Females	≤ 37 U/ml

It is important to keep in mind that establishment of a range of values which can be expected to be found by a given method for a population of "normal" persons is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

14.0 PERFORMANCE CHARACTERISTICS

14.1 Precision

The within and between assay precision of the CA 15-3 AccuLite® CLIA test system were determined by analyses on three different levels of control sera. The number, mean value, standard deviation (σ) and coefficient of variation for each of these control sera are presented in Table 2 and Table 3.

TABLE 2
Within Assay Precision (Values in U/ml)

Sample	N	X	σ	C.V.
Level 1	20	20.9	1.91	9.1%
Level 2	20	61.7	2.03	3.3%
Level 3	20	96.9	2.67	2.8%

TABLE 3
Between Assay Precision* (Values in U/ml)

Sample	N	X	σ	C.V.
Level 1	10	22.2	2.0	9.1%
Level 2	10	58.5	3.85	6.6%
Level 3	10	104.6	9.33	8.9%

*As measured in ten experiments in duplicate.

14.2 Sensitivity

The CA 15-3 AccuLite® CLIA Test System procedure has an analytical sensitivity of 0.2 U/ml at three (3) SD from the zero calibrator. The sensitivity was ascertained by determining the variability of the '0' calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose. The functional sensitivity (20% CV) was found to be 1.71U/ml.

14.3 Accuracy

The CA 15-3 AccuLite® CLIA Test System procedure was compared with a reference method. Biological specimens from low, normal, and elevated concentrations were assayed. The total number of such specimens was 43. The least square regression equation and the correlation coefficient were computed for the CA 15-3 in comparison with the reference method. The data obtained is displayed in Table 4.

TABLE 4

Method	Mean	Least Square Regression Analysis	Correlation Coefficient
This Method (Y)	180.2	y = -0.219 + 1.008 (x)	0.999
Reference (X)	178.6		

14.4 Specificity

In order to test the specificity of the antibody pair used in the CA 15-3 AccuLite® CLIA Test System, massive concentrations of possible cross-reactants were added to known serum pools and assayed in parallel with the base sera. No cross reaction was found. Percent cross-reactions for some of these additions are listed below in Table 5.

TABLE 5

Analyte	Concentration	Interference
CA 15-3	-	1.000
CA 125	10000 U/ml	0.001
CA 19-9	5000 U/ml	0.001
PSA	1000 ng/ml	0.026
AFP	30,000 ng/ml	ND*
CEA	5,000ng/ml	ND*
HCG	125,000mIU/ml	ND*
RF	12,000 IU/ml	0.001
Bilirubin	200 µg/ml	ND*
Hemolysis	30 µl/ml	ND*
Lipids	50 µg/ml	-0.009

15.0 REFERENCES

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5. Duffy MJ, 'Biochemical markers in breast cancer: which ones are clinically useful', *Clin Biochem*; 34, 347-352 (2001).
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11. Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, HHS Publication No. (CDC) 88-8395 (1988).
12. NCCLS. "Assessment of Laboratory Tests When Proficiency Testing is Not Available; Approved Guidelines.' (2008).

16.0 AVAILABLE CONFIGURATIONS

Available test-system sizes and included materials are shown below. Each "pack size" has a unique item/SKU number, which includes the product code. For the standard pack size of 96-microwells, the product code will have the letter "A" added (e.g., 5675-300A) to make a SKU for sale. This test kit is currently available as per below (with contents shown in table):

ITEM #	DESCRIPTION
5675-300A	CA 15-3 AccuLite CLIA Kit - 96 wells
5675-300B	CA 15-3 AccuLite CLIA Kit - 192 wells

Size		96(A)	192(B)
Reagent (fill)	A)	1ml set	1ml set
	B)	1 (12ml)	2 (12ml)
	C)	1 (12ml)	2 (12ml)
	D)	1 plate	2 plates
	E)	1 (20ml)	1 (20ml)
	F)	1 (50ml)	2 (50ml)
	G)	1 (7ml)	2 (7ml)
	H)	1 (7ml)	2 (7ml)

Also Available: QSure® Tumor Marker Control

Revision: 4 **Date: 2025-NOV-14** **DCO: 1747**
MP5675.4 **Product Code: *5675-300***

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IVD 2°-8° CE

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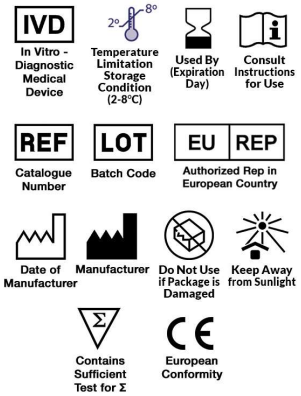
Glossary of Symbols
(ISO 15223)