Human Squamous Cell Carcinoma antigen CLIA Kit

Chemiluminescence Immunoassay for the quantitative determination of Squamous cell Carcinoma antigen in human serum

REF SKT-030 CE IVD 100,150 +2 +8 °C

INTENDED USE

Human Squamous Cell Carcinoma Antigen CLIA Kit is a Chemiluminescence Immunoassay (CLIA) intended for the quantitative measurement of human Squamous Cell Carcinoma concentration in serum.

For in-vitro diagnostics purposes only

SUMMARY OF PHYSIOLOGY

Squamous Cell Carcinoma（SCC）antigen, a glycoprotein tumor marker, is an antigen from cervical Squamous Cells and detected clinically in serum. Squamous Cell carcinoma antigen in the serum may be elevated in patients with cervical cancer, non-small cell lung cancer, skin cancer, head and neck cancer, digestive system tumors, and urinary tract tumors. This assay can be used in the surveillance and monitoring of recurrence or success of treatment of these diseases.[123]

ASSAY PRINCIPLE

The Human Squamous Cell Carcinoma antigen CLIA Kit is designed, developed, and produced for the quantitative measurement of human SCC levels in serum samples. The assay utilizes a two-site “sandwich” technique with two antibodies that bind to different epitopes of SCC.

Assay calibrators, controls, or patient serum samples are added directly to a reaction vessel together with magnetic particles antibody. The magnetic particles capture the SCC in the form of “magnetic particles–SCC antibody–SCC–acridinium ester SCC antibody”. Materials bound to the solid beads are held in a magnetic field while unbound materials are washed away. Then trigger solutions are added to the reaction vessel, and light emission is measured with the ECL100 or ECL 25 analyzer. The relative light units (RLU) are proportional to the concentration of a SCC in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve and reported in serum SCC concentration.

REAGENTS: PREPARATION AND STORAGE

This test kit must be stored at 2 – 8°C upon receipt. For the expiration date of the kit refer to the label on the kit box. All components are stable until this expiration date. It can be stored for 1 month at 2℃~8℃ after kit opening.

1. SCC Magnetic Particle Solution (03001)
Qty: 6.0 mL (100/kit), 8.5 mL (150/kit)
Storage: 2 – 8°C
Preparation: Ready to Use

2. Acridinium ester SCC antibody (03003)
Qty: 6.0 mL (100/kit), 8.5 mL (150/kit)
Storage: 2 – 8°C
Preparation: Ready to Use

3. SCC Calibrators (03006-03008)
Qty: 3 x vials
Storage: 2 – 8°C
Preparation: Ready to Use
After the first use, it is recommended to storage at 2 - 8℃ and can be used within one month. Do not freeze.

4. SCC Controls (03009-03010)
Qty: 2 x vials
Storage: 2 – 8°C
Preparation: Ready to Use
After the first use, it is recommended to storage at 2 - 8℃ and can be used within one month. Do not freeze.

SAFETY PRECAUTIONS

The reagents must be used in a professional laboratory environment and are for in vitro diagnostic use. Source material which contains reagents of bovine serum albumin was derived in New Zealand. It was obtained only from healthy donor animals, maintained under veterinary supervision, and found free of contagious diseases. Wear gloves while performing this assay and handle these reagents as if they were potentially infectious. Avoid contact with reagents containing hydrogen peroxide. Do not get in eyes, on skin, or on clothing. Do not ingest or inhale fumes. On contact, flush with copious amounts of water for at least 15 minutes. Exercise Good Laboratory Practices.

MATERIALS REQUIRED BUT NOT PROVIDED

1. ECL100 Immunoassay Analyzer (ECL100) or ECL25 Immunoassay Analyzer (ECL25)
2. CL011 Cuvettes (for ECL100) or CL010 Cuvettes (for ECL25)
3. EDI™ Wash Reagent (P-594)
4. EDI™ Trigger Solutions A and B (P-595A, P-595B)

The instrument must operate using materials supplied by Epitope Biotechnology, Co.,Ltd. or Epitope Diagnostics, Inc. When materials sourced from third-party suppliers are being used, Epitope Biotechnology, Co.,Ltd. and Epitope Diagnostics, Inc. take no responsibility for the validity of obtained results. Materials are available to purchase from Epitope Biotechnology, Co.,Ltd. and Epitope Diagnostics, Inc. Please contact your distributor for more information.

SPECIMEN COLLECTION AND PREPARATION

1. Blood sample should be collected under sterile conditions.
2. For human serum samples only; other body fluids and samples may not yield accurate results.
3. Clinical samples should be tested within 2 hours after collection. If the measurement cannot be completed within 2 hours, please store under the following conditions:
   - storage at low temperature and away from light (2℃~8℃) for 2 days,
   - storage at -20℃ or below for 6 months
   - Freeze and thaw only once
4. Avoid heat-inactivated samples. Mixed, contaminated and hemolysis samples should be discarded.
5. Samples should be restored to room temperature before testing. Frozen samples should be completely melted and mixed well before use. Due to possible

volatilization, samples, calibrators and controls on the ECL platform should be tested within 2 hours.

6. Some substances in the samples will interfere with the test results. The common interfering substances and maximum allowable concentrations are as follows:
   - bilirubin: 10 mg/mL
   - triglyceride: 1800 mg/mL
   - hemoglobin: 500 mg/mL
   - For patients receiving high-dose biotin therapy (5 mg/ day), samples must be collected 8 hours after taking the last dose of biotin.
7. A single assay of this item requires 20 µL of sample. This quantity does not include the amount of dead volume in the sample container, the capacity required for retesting, and other measurement items. For the definition of minimum required sample size, refer to the equipment manual.

CALIBRATION

An active calibration curve is required for all tests. Calibration is required for the first time use of a reagent lot and every 14 days thereafter or when either kit control is out of range. Refer to appropriate system manuals for configuring calibrators.

QUALITY CONTROL

The characteristics of patient samples are simulated through controls and are critical to validate the performance of CLIA assays due to the random access format. Use of controls is left to the discretion of the user based on good laboratory practices, requirements, and applicable laws. We suggest performing a control test once every day. Quality control results that do not fall within acceptable ranges may indicate invalid test results.

ASSAY PROCEDURE

1. Reagents from different kit lot numbers should not be combined or interchanged. Make sure that there are no air bubbles in any reagents, calibrator and control vials.

2. Reagent Preparation

2.1 Remove reagent cartridges from packaging and replace the solid caps with the provided soft caps for ECL100. For ECL25, carefully remove the aluminum foil seal on each container on the cartridges and insert soft caps.

2.2 For the ECL100, take out the Magnetic Particle bottle make sure to roll between hands and gently but thoroughly mix until the magnetic particle solution is homogenous. The solution should be uniform with no clumps of magnetic particles visible; this step is vital for assay performance. For ECL25, mix the magnetic beads by moving back and forth the bottom part of the cartridge at upright position. Make sure to look inside the cartridge until the solution is uniform with no clumps of magnetic particles visible and no air bubbles. Recap the bottle. Open the top soft cap of all reagent bottles, leaving only the hollow soft rubber. The reagents are now ready to be loaded into the ECL100 or ECL 25 for calibration.

3. Assay Program

The following table illustrates the protocol used by the ECL100 or ECL25 for instrument operation.

Component	**Quality Control Hole (µL)**	**Sample Hole (µL)**
SCC Controls (03009-03010)	20	-
Samples	-	20
SCC Magnetic Particle Solution (03001)	50	50
Acridinium ester SCC antibody (03003)	50	50
Incubate at 37°C for 15 minutes		
Wash the reaction cuvette 3 times with wash reagent.		
Trigger Solution A (P-595)	100-200	100-200
Trigger Solution B (P-595)	100-200	100-200

NOTE FOR ASSAY PROCEDURE

Reagents from different kit lot numbers should not be combined or interchanged. Make sure that there is no air bubble in any reagents, calibrator and control vials.

All the reagents in this kit are ready-to-use. Different lots of the same reagents are not inter-changeable and must not be used.

Please read the reagent instructions and equipment instructions carefully before using this kit and perform the test according to relevant requirements. When reagents are loaded, the equipment will automatically stir the magnetic particles to resuspend them. Allow the regent to mix for minimum 15 min before starting the assay program.

INTERPRETION OF RESULTS

1. The default unit for the Squamous Cell Carcinoma project is ng/mL.

2. Due to methodological differences or antibody specificity, there may be deviations between the test results of reagents from different manufacturers. Therefore, direct comparisons should not be made to avoid false interpretation.

3. When the concentration of SCC in the sample exceeds 70.0 ng/mL, the sample can be diluted before detection

4. When the sample concentration of Squamous Cell Carcinoma antigen is lower than the detection lower limit, the test result will be reported as < 0.10ng/mL. When the sample concentration is higher than the detection upper limit, it will be reported as >70ng/mL.

EXPECTED VALUES

The SCC test reagent was used for single tests on serum samples of people receiving health examination. (The test results are for reference only as the health status of those people is unknown due to resource constraints.) A normal range was established with the serum samples as below.
In this study, a total of 200 serum samples from physical examination population were tested, and their concentration distribution is shown in the table above. The results show that 95% of the test samples have SCC values lower than 2.34 ng/mL and 97.5% have SCC values lower than 2.58 ng/mL.

Concentration range	N	Median	95th percentile	97.5th percentile
＞1.5ng/mL	55	1.19 ng/mL	2.34 ng/mL	2.58 ng/mL
＞2.3ng/mL	12			
＞2.7ng/mL	2			

Note: each Laboratory is recommended to determine and establish its own reference range within the local population.

LIMITATIONS OF THE PROCEDURE

1. This product is for use on the ECL100 Immunoassay Analyzer or ECL 25 Immunoassay Analyzer only. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, operation, system performance, instructions, calibration, precautions, hazards, maintenance, and troubleshooting.
2. Reagents from different kit lot numbers should not be combined or interchanged.
3. Test results obtained from the proposed kit should not be served as a sole basis for clinical diagnosis or patient management.
4. If the test sample result is higher than the upper limit of the calibration curve, it is recommended to re-measure after dilution according to a certain ratio. The measured value is recalculated according to the dilution ratio to ensure the accuracy of the result.

PERFORMANCE CHARACTERISTICS

1. **Hook Effect:**
   - The assay showed no hook effect up to 5803 ng/mL
2. **Limit of Detection(LoD):**
   - ≤0.200 ng/mL
3. **Linearity:**
   - 0.200 ng/mL to 70.0 ng/mL
   - linearity correlation coefficient R ≥0.990
4. **Accuracy:**
   - relative deviation within ±10%
5. **Precision:**
   - Intra-assay repeatability: CV≤8%
   - Inter-assay reproducibility: CV≤15%

NOTES

1. Read the instructions carefully and gently but thoroughly mix the reagent before use. Remove any air bubbles before loading the reagents onto the equipment.
2. Keep the reagent in the storage conditions indicated in this IFU and on the reagent label. Do not freeze reagents.
3. Avoid contact with skin, eyes and mucous membrane. Upon contact, flush the area with clean water immediately.
4. All patient samples must be treated as potential infectious material.
5. Components in different kits cannot be mixed.
6. All waste must be disposed of in compliance with local regulations and laws

WARRANTY

This product is warranted to perform as described in its labeling and literature when used in accordance with all instructions. Epitope Biotechnology Co,Ltd and its distributors DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, and in no event shall Epitope Biotechnology Co,Ltd.. be liable for consequential damages. Replacement of the product or refund of the purchase price is the exclusive remedy for the purchaser. This warranty gives you specific legal rights and you may have other rights, which vary from state to state.

REFERENCE

1.Chen Y M, Wang L, Zhong L H, et al. Application of tumor markers in the early diagnosis of ovarian cancer (J). Current Medicine,2012; 18 (20) : 12-3.
2.Chen Jing-jing, Chen Jian-min, Sun Quan. Clinical significance of CEA, CK19 and SCC in diagnosis of lung cancer [J]. Modern immunology, 2017,37 (3) : 22.
3.Zhu Lin,GUOGuang-hong,Evaluation of ChemiluminescentMicroparticle Immunoassay for Detection of Squamous Cell Carcinoma Antigen,Labeled Immunoassays and Clinical Medicine,2016, 23(10).

TECHNICAL ASSISTANCE AND CUSTOMER SERVICE

For technical assistance or to place an order, please contact Epitope Diagnostics, Inc. in USA at +1 858-693-7877 or email to cs@epitopediagnostics.com

Epitope Biotechnology, Co.,Ltd.
599 Yazhong Rd. 3-4F, Jiaxing
Zhejiang 314006, China

This product is marketed by
Epitope Diagnostics, Inc.
7110 Carroll Rd
San Diego, CA 92121 United States
www.epitopediagnotics.com

MDSS GmbH
Schiffgraben 41,
30175 Hannover, Germany

GLOSSARY OF SYMBOLS (EN 980/ISO 15223)

In Vitro Diagnostic Device

European Conformity

Lot Number

Catalog Number

Read Instructions before Use

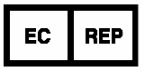
Number of Tests

Store at

Use by

Keep Away from Heat and Direct Sun light

Manufacturer



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