Lifotronic

CE

Instruction for Use

【Product Name】

Squamous Cell Carcinoma (eCLIA)

【Order Information】

REF NO.	Package Size
0320501201	50T
0320501202	2×50T
0320501203	100T
0320501204	2×100T

【Intended Use】

Squamous Cell Carcinoma (eCLIA) is an immunoassay reagent for in vitro quantitative determination of Squamous Cell Carcinoma (SCC) in human serum and plasma by Automated ECL Analyzer to aid diagnosis of cervical cancer, non-small cell carcinoma.

【Summary】

Squamous cell carcinoma (SCC) is a malignant tumor of squamous epithelium. Squamous cell carcinoma antigen (SCCA) is a subfragment of TA-4. This protein is a kind of cancer antigen[1], and a glycoprotein with a molecular weight of 42 KDa[2]. Ta-4, obtained from SCC tissues of the cervix, is characterized as the glycoprotein with a molecular weight of 48 KDa and consists of at least 14 subfragments. SCCA exists in normal squamous epithelium and is massively produced in malignant proliferative squamous epithelium and released into the blood[3]. Elevated serum SCCA level has been found in malignant tumors such as cervical cancer, lung cancer, head and neck malignant tumors, esophageal cancer and anal cancer, and also in non-malignant skin diseases and renal failure[4].

Studies on squamous cell carcinoma have shown that in lung cancer and cervical cancer patients, the more advanced the cancer, the higher the level of SCCA. Continuous SCCA monitoring helps assess the recurrence of the disease, residual disease after treatment and therapeutic response[5, 6].

It is used for quantitative determination of SCC in human serum or plasma in vitro. For professionals use only.

【Principles of the testing method】

Sandwich principle. Total duration of assay: 9 minutes.

The Squamous Cell Carcinoma (SCC) Assay Kit adopts the double-site sandwich electrochemiluminescence method. SCC in the sample, biotinylated SCC monoclonal antibody and the ruthenium (Ru) complex-labeled SCC monoclonal antibody form an antigen-antibody sandwich complex, which is bound to streptavidin coated magnetic particles, and then transferred to the measuring cell where the magnetic particles are captured onto the surface of the electrode, while the unbound substances are washed away. Chemiluminescence is generated after the electrode is electrified, and the generated optical signal is measured by a photomultiplier, processed by an instrument, and the concentration of SCC in the sample is calculated based on the calibration curve.

【Main Components】

The reagent pack consists of MB, RA, RB, calibrators and control materials (optional), and different components and reagents of lot numbers should ne be used interchangeably.

Components	Ingredients	Volume (50T)	Volume (2×50T)	Volume (100T)	Volume (2×100T)
MB	Streptavidin coated magnetic particles, 0.45 mg/mL; 0.1M phosphate-buffered saline (PBS); ProClin300	1×1.8mL	2×1.8mL	1×3.5mL	2×3.5mL
RB	Biotinylated SCC antibody, 1.0 mg/L; 0.1M phosphate-buffered saline (PBS); ProClin300	1×3.0mL	2×3.0mL	1×6.0mL	2×6.0mL
RA	Ru complex-labeled SCC antibody, 1.0 mg/L; 0.1M phosphate-buffered saline (PBS); ProClin300	1×3.5mL	2×3.5mL	1×7.0mL	2×7.0mL
Calibrator (High)	SCC antigen, 0.1M phosphate-buffered saline (PBS); ProClin300	1×1.0mL	2×1.0mL	1×1.0mL	1×1.0mL
Calibrator (Low)	SCC antigen, 0.1M phosphate-buffered saline (PBS); ProClin300	1×1.0mL	2×1.0mL	1×1.0mL	1×1.0mL
Control Material (High) (Optional)	SCC antigen, 0.1M phosphate-buffered saline (PBS); ProClin300	1×1.0mL	2×1.0mL	1×1.0mL	1×1.0mL
Control Material (Low) (Optional)	SCC antigen, 0.1M phosphate-buffered saline (PBS); ProClin300	1×1.0mL	2×1.0mL	1×1.0mL	1×1.0mL

The assignment process of supporting calibrators in this pack is strictly implemented with reference to ISO 17511:2020, which can be traced to Roche Elecsys SCC.

Refer to the quality control card for the target value and range of the quality controls.

Supporting instruments and materials required but not provided in this pack:

Additional materials for Automated ECL Immunoassay Analyzer eCL8000, eCL8000i, eCL8000p, eCL8000x:

- Auffer, 480 mL, 6×480 mL
- Buffer, 480 mL, 6×480 mL
- Concentrated Washing Buffer
- Assay Cup

Additional materials for Automated ECL Immunoassay Analyzer eCL9000, eCL9000i, eCL9600, eCL9900, eCL9900i:

- Auffer, 2 L
- Buffer, 2 L
- Concentrated Washing Buffer
- Assay Cup, reaction cup
- Disposable Sampling Head, pipette tips
- PreClean, system wash solution
- Waste Bags, litter bags

【Storage and Shelf Life】

Damaged, expired or contaminated reagents should be discarded.

The kit should be stored at:

Stability	
Unopened at 2~8ºC	18 months
Store at 2~8ºC after opening	56 days
Stored onboard	56 days

【Applicable Instrument】

Automated ECL Immunoassay Analyzer: eCL8000, eCL8000i, eCL8000p, eCL8000x, eCL9000, eCL9000i, eCL9600, eCL9900, eCL9900i.

【Specimen collection, preparation and storage】

It is recommended to use human serum samples or plasma samples collected with EDTA-K2, EDTA-K3, heparin lithium blood collection tubes.

Blood samples should be collected in accordance with the standard operation of venipuncture. After the sample is completely coagulated, centrifugation should be performed to remove residual cellular substances. The sample should be free of air bubbles during testing. Lipid layer covering the sample after centrifugation should be removed. It is not recommended to use hemolyzed samples.

Samples can be stored for 5 days at room temperature (18~28℃), 14 days at 2~8℃, and 12 weeks at -15℃ or below. Samples can be freeze-thawed only once.

【Testing Procedure】

Testing procedure and precautions

Before testing, the system operation manual of the measuring instrument should be carefully read, so as to obtain relevant information such as system operating procedures, sample management, safety precautions and maintenance, and materials required for testing should be prepared. SCC testing procedures should be called and set up in accordance with the system operating procedures.

Before using the reagent, put it into the analyzer 30 minutes in advance to automatically stir the magnetic bead particles and keep them in suspension.

Recommended environment temperature for testing: 10~30℃; relative humidity: ≤80%.

The SCC test adopts the double-site sandwich electrochemiluminescence method, with the total test time of 9 minutes, and the test method is as follows:

Step 1: After the user applies for testing, the system automatically aspirates 60 μL of biotinylated SCC monoclonal antibody, 70 μL of Ru complex-labeled SCC monoclonal antibody, 35 μL of streptavidin coated magnetic particles and 15 μL of sample into the reaction cup. They are automatically incubated at 37℃ for 9 minutes to form antigen-antibody sandwich complexes, and then the whole complexes are bound to the magnetic particles under the interaction of biotin and streptavidin.

Step 2: After incubation, the system automatically aspirates the reaction mixture into the measuring cell, the magnetic particles are captured onto the surface of electrode, while the unbound substances are washed away by buffer, and the electrodes is applied with voltage to generate chemiluminescence. The generated optical signals are measured by the photomultiplier, and the measured results are automatically determined via the calibration curve specifically generated by the instrument (this curve is obtained by performing two-point calibration for the master calibration curve obtained by reading the reagent RFID).

Calibration

Calibration should be performed using the lot-matching reagent and calibrators.

The target value of the calibrator has been written into the Radio-Frequency Identification card (RFID card) of the kit.

1. Before calibration, the target value, reagent information and master calibration curve information of the calibrator in the RFID card (Radio Frequency Identification, inductive electronic chip or proximity card) of the kit should be imported into the test system by swiping the card.

2. The supporting calibrator is tested, and the analyzer adjusts the master calibration curve according to the test results of the supporting calibrator to obtain the calibration curve tested by the current system (the analyzer can automatically interpret the validity of the calibration curve according to the adjustment results).

The test system should re-perform the calibration operation under the following conditions:

(1) When different lots of reagents are used;
(2) When the same lot of reagents has been used on the analyzer for more than 28 days;
(3) According to requirements: e.g. if the quality control result exceeds the defined limit.
(4) When changing the buffers of different lot numbers.

Quality Control procedure

In order to ensure the reliability of test results, it is recommended to test the control materials every 24 hours. It is recommended to test the control materials after each calibration, reagent lot replacement, maintenance or troubleshooting. The quality control results should all fall within the defined range. If they exceed the defined range, the reasons such as instrument status, reagents and calibrators should be investigated and the corrective measures should be taken.

Calculation

The system software can automatically calculate the analyte concentration, with the result in ng/mL.

Specimen dilution

SCC concentration in the sample higher than the upper limit of detection can be diluted manually with sample diluent.

The recommended dilution ratio is 1:20. The results are reported by multiplying the measured values by the dilution ratio.

【Biological Reference Interval】

By analyzing the serum samples of 240 healthy population from hospitals, it was calculated that the upper limit of the reference range of 95% is 2.742 ng/mL.

Due to the differences in geography, race, gender and age, it is recommended that each laboratory determine the applicability of reference range through tests, and establish the reference range of this laboratory if necessary.

【Interpretation of results】

When interpreting the test results, it is necessary to refer to the patient's overall clinical situation, including: symptoms, medical history as well as other corresponding data and information.

【Limitations】

1. Test results are used only for clinical reference and cannot be used alone as the basis for diagnosis or exclusion of cases.
2. The detection range of the kit is 0.03~70 ng/mL. If the SCC concentration in the sample is lower than the lower limit of detection, the result is reported as less than this value (for example, <0.03 ng/mL); if the SCC concentration in the sample is higher than the upper limit of detection, the result is reported as greater than this value (for example, >70 ng/mL), or the sample is manually diluted with sample diluent at the dilution ratio of 1:20, and the result is reported with the measured value multiplied by the dilution ratio.
3. When jaundice (bilirubin) is ≤20 mg/dL, hemolysis (hemoglobin) is ≤500 mg/dL, lipemia (triglyceride) is ≤1000 mg/dL, biotin is ≤35 ng/mL, total protein is ≤70 mg/mL, and HAMA is ≤90 ng/mL in the sample, the interference deviation of the measured results is within ±10%. When the concentration of rheumatoid factor in the sample is less than or equal to 1200 IU/mL, the relative recovery of the test results is between 90% and 110%.
4. Twenty-four kinds of drugs are added to the serum samples containing SCC to make interference samples, and the concentrations of drugs added are as follows: ascorbic acid (300 mg/L), cyclosporine (5 mg/L), methyldopa (20 mg/L), metronidazole (200 mg/L), butazodine (400 mg/L), acetylsalicylic acid (1000 mg/L), paracetamol (200 mg/L), ibuprofen (500 mg/L), theophylline (100 mg/L), 5-fluorouracil (900 mg/L), carboplatin (600 mg/L), cisplatin (180 mg/L), cyclophosphamide (500 mg/L), dexamethasone (20 mg/L), adriamycin (120 mg/L), erlotinib (150 mg/L), etoposide (300 mg/L), gefitinib (250 mg/L), gemcitabine (1500 mg/L), ifosfamide (7200 mg/L), methotrexate (150 mg/L), metoclopramide (7.5 mg/L), paclitaxel (265 mg/L) and vinorelbine tartrate (53.1mg/L), The SCC contents in the interference sample and the control sample (without drug addition) are measured respectively, and the relative deviation of the measured results is within ±10%.
5. When the SCC concentration reaches 2000 ng/mL, there is no high-dose hook effect; when the SCC concentration reaches 10000 ng/mL, the test results are not be affected by the hook effect.

【Analytical Performance】

Lower limit of measurement

Limit of Detection (LoD) ≤ 0.1 ng/mL.

Accuracy

Testing standard traceability of accuracy control products, the relative deviation of it's test results is within ±10%.

Linearity

Within the range of 0.1 ng/mL~70 ng/mL, the correlation coefficient (r) of the kit should not be less than 0.9900.

Within-run imprecision (repeatability)

The coefficient of variation (CV) ≤ 6%.

Between-lot imprecision

The coefficient of variation (CV) ≤ 10%.

Accuracy of calibrators

The supporting calibrators of the kit are tested, the relative deviation of their test results is within ±10%.

Measured values of quality control

The measured results of supporting assigned quality control of the kit should be within the quality control range.

Homogeneity of calibrator and quality control

Intra-vial homogeneity: Coefficient of variation (CV) ≤ 6%;

Inter-vial homogeneity: Coefficient of variation (CV) ≤ 10%.

【Precaution and Warning】

This kit is only used for in vitro diagnosis;

When using this kit, the relevant operation precautions of the laboratory must be observed;

The test results of this kit can only be used as clinical reference, the patient's clinical evaluation should be based on the patient's clinical symptoms/signs, medical history, other laboratory test results and treatment response, etc.;

Due to methodological reasons or antibody specificity, the results of the same sample tested with reagents of different manufacturers may be different. Therefore, results obtained with different kits should not be directly compared, so as to prevent wrong medical interpretation; it is recommended that the Laboratory Department indicate the characteristics of the reagents in the test report issued to the clinician. If the reagent type is changed during series monitoring, continuous testing should be conducted, and the results should be compared with the original reagent results in parallel to re-determine the baseline value;

This product contains animal-derived substances, and may have potential biological risks. All samples and reaction wastes should be treated as the source of infection, and all wastes must be disposed of in accordance with local regulations.

【References】

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【Version and revision】

Version: A0

Issue Date: 2021-1-13

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