Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA)

Summary of Safety and Performance

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Hangzhou Realy Tech Co., Ltd.

Contents

1 Device identification and general information

1.1 Device trade name

Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA)

1.2 Manufacturer's name and address

Hangzhou Realy Tech Co., Ltd.

#2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200, Hangzhou City, Zhejiang Province, China

0086-0571-56050793, 0086-0571-56050794, www.realytech.com

1.3 Manufacturer single registration number (SRN)

CN-MF-000004716

1.4 Basic UDI-DI

697179205C2KA001BS

1.5 Medical device reference codes

IVDR Code: IVP3007

EMDN Code: W0102039001 ALPHAFETOPROTEIN

1.6 Risk Class of device

Per the in vitro Diagnostic Regulation (IVDR, EU 2017/746) Article 2 and Annex VIII, the alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) is considered a Class C in vitro diagnostic device.

1.7 Initial certificate (CE) issuance

The initial CE registration as classification others according to Directive 98/79/EC for the product is 2021.

1.8 European authorized representative

CMC Medical Devices & Drugs S.L.

C/Horacio Lengo No 18 CP 29006, Málaga-Spain

+34951214054

European authorized representative single registration number (SRN)

SRN: ES-AR-000000293

1.9 Notified body

BSI Group, The Netherlands B.V.

NB ID: 2797

2 The intended purpose, contraindications and target populations of device

2.1 Indications for use/Intended purpose

The Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of alpha-fetoprotein (AFP) in human serum or plasma. It is mainly used to aid to diagnosis of hepatocellular carcinoma (HCC) or suspected patients disease progression or therapeutic effect, and cannot be used as the basis for the early diagnosis or diagnosis of malignant tumors.For laboratory professional use only.

The reagent itself is non-automated, but the instrument which is used together with the reagent is automated.

2.2 Target/Testing population

Hepatocellular carcinoma patients or suspected patients.

2.3 Indication whether it is a device for near-patient testing and/or a companion Diagnostic

The product is for a companion Diagnostic

2.4 Contraindications

There are no known contraindications for use.

3 Device description

3.1 Description of the device

The Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of alpha-fetoprotein (AFP) in human serum or plasma. It is mainly used to aid to diagnosis of hepatocellular carcinoma (HCC) or suspected patients' disease progression or therapeutic effect, and cannot be used as the basis for the early diagnosis or diagnosis of malignant tumors. For laboratory professional use only.

3.2 Description of the components

The Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) is composed of Micro-particles Buffer, Conjugate Buffer, Wash Buffer, Substrate Buffer, Calibrator and Quality control. It is non-sterilized. The model of this kit is 24 Tests/Kit, 30 Tests/Kit, 48 Tests/Kit and 60 Tests/Kit. It is designed for use on the REALY Analyzer System.

3.3 Previous generation(s) or variants

Not applicable.

3.4 Description of accessories

Not applicable.

3.5 Description of devices which are intended to be used in combination with the device

The Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) is intended be to used on the Realy Analyzer System.

4 Reference to harmonized standards and CS applied

Category	Standard	Description
Regulation	(EU) 2017/746	IVDR Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directives

			98/79/EC and Commission Decision 2010/227/EU.
Guidance	Common guidance	MDCG 2022-2	Guidance on general principles of clinical evidence for In Vitro Diagnostic medical devices (IVDs);
		MDCG 2022-9	Summary of safety and performance template
		MDCG 2020-16 Rev.2	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746
		Meddev 2.12-1 Rev.8	Guidelines on a medical devices vigilance system, published in Jan. 2013
	CLSI guidance	EP25-2nd Edition	Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
		EP05-A3-3rd Edition	Evaluation of Precision of Quantitative Measurement Procedures
		EP09c-3rd Edition	Measurement Procedure Comparison and Bias Estimation Using Patient Samples
		EP17-A2-2nd Edition	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
		EP28-A3c-3rd Edition	Defining, Establishing, and Verifying Reference Intervals in the Clinical

			Laboratory
		EP06-2nd Edition	Evaluation of Linearity of Quantitative Measurement Procedures
		EP34-1st Edition	Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking
		EP35-1st Edition	Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures.
		EP07-3rd Edition	Interference Testing in Clinical Chemistry
Standards	Harmonized standards	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems -Requirements for regulatory purposes
		EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
		EN ISO 15223-1:2021	Medical devices - Symbols to be used with medicaldevice labels, labelling and information to be supplied - Part 1: General requirements
		EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
		EN ISO 17511:2021	In vitro diagnostic medical devices -

			Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)
	Non-harmonized standards	EN 13612:2002/AC:2002	Performance evaluation of *in vitro* diagnostic medical devices
		EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
		ISO 18113-1:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1:Terms, definitions and general requirements
		ISO 18113-2:2022	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
		EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
		ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice

		ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers
		ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971

5 Risks and warnings

5.1 Residual risks and undesirable effects

The clinical benefit of the alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) is that it aids to diagnosis of hepatocellular carcinoma (HCC) or suspected patients' disease progression or therapeutic effect by measuring the AFP levels in patients' serum or plasma. The clinically relevant risk related to the product are those risks associated with misdiagnosis due to the intrinsic limited specificity of AFP in the diagnosis of HCC. But since the product is not intended to be used as the basis for early diagnosis, the clinical benefit outweighs the risks. In practice, healthcare professionals should always exercise caution when interpreting the results and consider clinical context, patient history, and other diagnostic tools to make informed decisions.

5.2 Warning and Precautions

1) For *In Vitro* Diagnostic Use.
2) Do not use expired or clearly damaged kits.
3) Operating according to the steps described, can make the risk of daily handling patients` samples and blood products into a minimum, however, no matter what the source of the products, handling mode or the previous proof, these potentially infectious substances were used shall be in accordance with the unified considerations and Good Laboratory Practice (GLP).
4) Proper disinfectant should be used to eliminate pollution.
5) Follow local rules and regulations to keep and dispose of these items and containers for these items.
6) The ProClin-300 is a potential skin sensitizer. Avoid dumping or splashing this reagent on your skin and clothing. In case of contact with this reagent, wash thoroughly with soap and

water.

7) Avoid foam formation in all reagents and sample types (specimens, calibrators and quality controls).
8) The reagents should be kept away from light, and unused reagents should be put back into the kit in time and be careful to avoid light.
9) If the reagent is turbid or cannot be mixed evenly, the reagent will not be usable.
10) This product can only be used by testing personnel.
11) This product is only for one-time use and cannot be reused.
12) When any serious incidents occur, they should be reported to the manufacturer and competent authorities.

5.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN)

No.

6 Summary of performance evaluation and post-market performance follow-up (PMPF)

6.1 Summary of scientific validity of the device

Hepatocellular Carcinoma (HCC) and AFP as a Biomarker

Alpha-fetoprotein (AFP) is a glycoprotein primarily produced during fetal development by the yolk sac and liver, with minimal levels in healthy adults (<10 ng/mL). Elevated AFP levels are a critical biomarker for hepatocellular carcinoma (HCC) and play a role in diagnosis, prognosis, treatment monitoring, and surveillance.

Diagnostic Role

AFP aids in diagnosing HCC, particularly in high-risk individuals such as those with chronic hepatitis or cirrhosis. While benign liver conditions may cause mild AFP elevations (10–200 ng/mL), levels >400 ng/mL strongly suggest HCC when imaging confirms a liver mass. Combining AFP with imaging (e.g., ultrasound, CT, MRI) improves diagnostic accuracy. However, AFP has limited sensitivity for early-stage HCC and is often integrated with additional biomarkers like DCP or AFP-L3% for enhanced detection.

Prognostic Utility

AFP levels correlate with tumor burden, vascular invasion, and metastatic potential, serving as a valuable prognostic tool. Elevated AFP (>1,000 ng/mL) is associated with aggressive tumor behavior and worse survival rates. Monitoring AFP trends during treatment helps assess disease status, with rising levels indicating progression or recurrence, and decreasing levels suggesting positive treatment response.

Monitoring Treatment Response

AFP is reliable for evaluating therapeutic outcomes. Locoregional therapies, surgical resection, or systemic treatments typically reduce AFP levels if effective. Persistent or rising AFP may indicate residual disease or recurrence. AFP trends are also used to monitor responses to systemic therapies like tyrosine kinase inhibitors or immune checkpoint inhibitors.

Surveillance Role

AFP is incorporated into surveillance programs for high-risk populations (e.g., those with HBV, HCV, or cirrhosis). Serial AFP measurements, combined with imaging (e.g., ultrasound), improve sensitivity for detecting early-stage HCC. However, false positives due to benign conditions necessitate combining AFP with other biomarkers and imaging modalities.

6.2 Summary of performance data from equivalent device

6.3.2.2 Clinical evidence from literatures of equivalent device

All evidences demonstrate that the product meet the claimed clinical performance

The clinical evaluation results are presented as below:

The Elecsys AFP Assay Reagent Kit demonstrates clinical utility in hepatocellular carcinoma (HCC) diagnosis and management, as supported by published evidence. Its performance fulfills the intended purposes of aiding diagnosis, providing prognostic insights, and monitoring treatment response.

1. Evidence Supporting the Intended Use

(1) Aid to Diagnostic Role

The Elecsys AFP Assay Kit is effective in aiding the diagnosis of HCC, particularly when combined with other diagnostic modalities.

Supporting Evidence:

Article #1 highlights acceptable sensitivity but moderate specificity for AFP at a 200 ng/mL cutoff, underscoring the need to combine AFP testing with additional biomarkers for improved accuracy, especially in early-stage or AFP-negative HCC.

Article #2 demonstrates that the Elecsys assay achieved 86.9% sensitivity and 83.7% specificity for detecting small (<2 cm), hypovascular, and hypervascular HCCs at a cutoff of 28.4 ng/mL. This validates its role in identifying challenging cases.

Article #3 reports that combining free AFP with AFP-IgM immune complexes significantly enhances specificity and reduces false positives/negatives in early-stage HCC diagnosis.

(2) Prognostic Utility

The kit provides prognostic insights into HCC progression by correlating AFP levels with tumor burden, invasion, and recurrence.

Supporting Evidence: Persistently elevated AFP levels after treatment indicate incomplete tumor control or recurrence, while decreasing levels suggest a positive therapeutic response. These

trends align with the predictive capability described in Article #1 and Article #3, making AFP a valuable tool for prognosis and treatment planning.

(3) Monitoring Treatment Response

AFP serves as a reliable biomarker for tracking therapeutic outcomes in patients undergoing treatments such as surgical resection, locoregional therapies, or systemic treatments.

Supporting Evidence:

The Elecsys assay has demonstrated favorable analytical performance for detecting changes in AFP levels post-treatment. Article #2 validates its capability to monitor tumor dynamics effectively.

Rising AFP levels signal disease progression or recurrence, while decreasing levels reflect treatment success, as supported by multiple clinical scenarios in the literature.

2. Benefit/Risk Profile

Benefits:

High Sensitivity in Key Contexts: The assay is particularly effective in detecting HCC when combined with imaging and other biomarkers, making it suitable for high-risk populations (e.g., patients with chronic hepatitis or cirrhosis).

Prognostic and Monitoring Value: By correlating AFP levels with disease progression and treatment outcomes, the kit aids clinicians in making informed decisions about patient care.

Reliable Analytical Performance: Clinical studies confirm its strong agreement with marketed assays, ensuring consistency and accuracy in clinical settings.

Risks:

Variable Specificity: False positives or negatives may occur, particularly in benign liver conditions (e.g., cirrhosis, chronic hepatitis). This necessitates cautious interpretation and the integration of AFP results with other diagnostic tools.

Limited Standalone Utility: The assay is not intended for definitive diagnosis or early detection of malignancies, requiring a broader diagnostic framework for comprehensive evaluation.

Conclusion:

The Elecsys AFP Assay Reagent Kit offers significant benefits in HCC diagnosis and management, with its high sensitivity, prognostic value, and ability to monitor treatment response. While specificity challenges and standalone limitations exist, these are mitigated by integrating the assay into a broader diagnostic strategy. Overall, the kit's benefit/risk profile is acceptable and supports its continued use in clinical practice.

6.3 Summary of performance data from conducted studies of the device prior to CE marking

• 6.3.1 Analytical sensitivity (LOB/LOD/LOQ):

Two batches of reagents were used to test 5 blank samples for three days. Each sample was tested 4 times each day. As the data is normal distribution, the parameter analysis method is applied to calculate the LOB. And the LOB of the product is 0.12ng/mL.

Two batches of reagents were used to test 5 low-concentration samples for three days. Each sample was tested 4 times each day. As the test results are normally distributed and the variance is equal, the parameter analysis method is applied to calculate the LOD. And the LOD of the product is 0.18ng/mL.

Data obtained from LOD was analyzed and TE%>TE% target value, LOQ ≠ LOD. So two batches of reagents were used to test 5 low-concentration samples at the expected target LOQ concentration for three days. Each sample was tested 3 times each day. Calculate the average value of detection(X); SD and TE for each sample. And the LOQ of the product is 0.50ng/mL.

• Analytical specificity

One batch of reagents was used to test interference samples and control samples separately, with each sample being tested three times. The analysis was conducted by calculating measurement deviations to determine the presence of interference.

After adding interfering substances to the samples, the relative deviations between the test results and the control samples all meet the acceptable standards, indicating that interfering substances at concentrations not higher than the following have no impact on the test results of this product.

Interfering substance	Experimental concentration
Bilirubin	65 mg/dL
Hemoglobin	2.2 g/dL
Triglycerides	1500 mg/dL

Sodium heparin	0.625 mg/mL
Lithium heparin	0.625 mg/mL
Potassium EDTA	6 mg/mL
Sodium EDTA	6 mg/mL
Rheumatoid Factor	1500 IU/mL
ANA	1:200000
HAMA	200 IU/mL
IgG	7 g/dL
Albumin	7 g/dL
Ascorbic acid	52.5 mg/L
Acetaminophen	156 mg/L

- Precision

Serum samples with low (6 – 8ng/mL), medium (200 – 300ng/mL) and high (800 – 1000ng/mL) concentrations are prepared for this test. For the within-laboratory precision test, three serum samples of different concentrations and two Quality Controls are tested by the same operator on the same instrument, with two batches of each sample tested per day, with a minimum of 2 hours between batches, and two replicates of each sample per batch, for a total of 20 days (not necessarily consecutive). For the reproducibility test, three serum samples of different concentrations and two quality controls, by three operators in three different laboratories using three different instruments, 5 tests are repeated per day for each sample on each instrument for 5 consecutive days.

According to the experimental results of within-laboratory precision and reproducibility, all of them are in line with the acceptable criteria (CV≤ 8%), and the product precision is good.

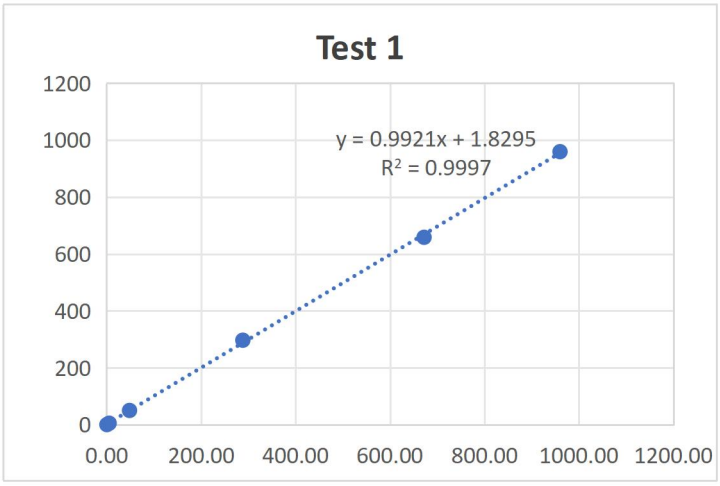
• Accuracy

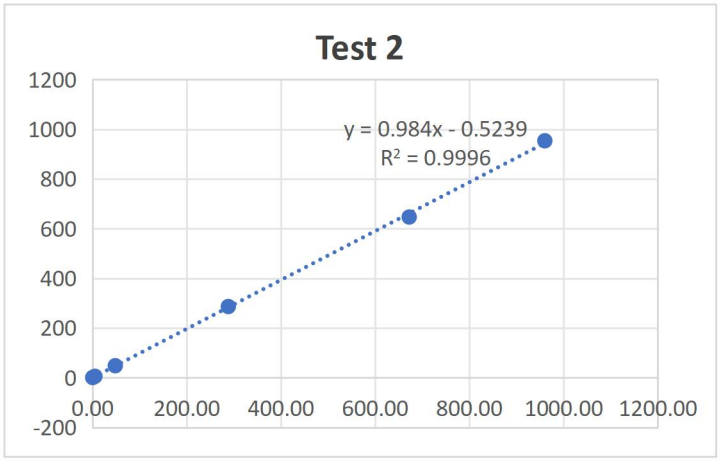
Accuracy will be determined by testing certified AFP International standard in low (6 – 8ng/mL), medium (200 - 300ng/mL) and high (800 – 1000ng/mL) concentration range using Realy alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA).

The relative deviations of the measured value from the target value of the AFP international standard product were all within ±10.0%, and the accuracy of the product was good.

• Linearity

One high serum specimen at a concentration of 1200-1300ng/mL and one low serum specimen at a concentration around the LOQ are prepared. Another nine samples of different concentrations are prepared by proportionally mixing a sample high with a sample low. Each sample is tested 3 times. Using polynomial regression to evaluate the linearity of a measurement procedure. Combined with the actual situation of the testing system, the allowable imprecision is ≤ 8% and the allowable error is ≤ 10% when establishing the linearity interval.





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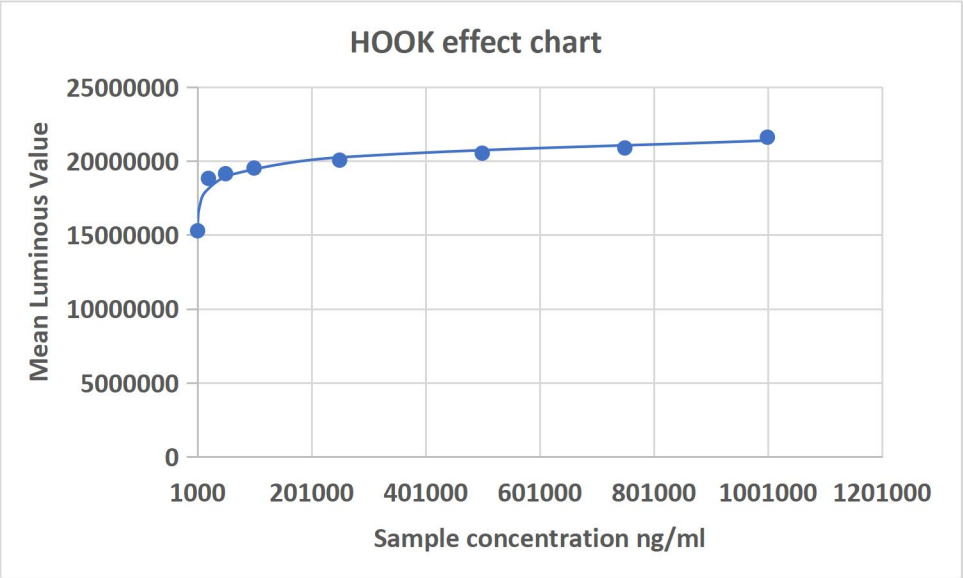
The linear correlation coefficient r > 0.9900 and the relative deviation of each measured value are less than 10%, so the linear interval and measurement interval is established as 0.50-1000ng/mL.

- • Recommended Dilution Ratio

3 serum samples with known concentrations close to 1000ng/mL are diluted with diluent at four dilution ratio of 1:2; 1:4; 1:10; 1:20. One batch of reagents is used to test the four diluted serum samples and each sample is tested 3 times and calculate the mean value and the recovery of the measured concentration and the theoretical concentration. The recoveries of the measured concentration and the theoretical concentration of the samples manually diluted at 1:2, 1:4 and 1:10 are within 90 ~ 110%, in which the dilution ratio of 1:10 is the maximum dilution ratio.

• High dose hook effect

A series of Hook samples with gradient concentrations were prepared that the lowest concentration was about the upper limit of the linear range, and the highest concentration was the highest possible concentration in clinical practice. Repeat the test three times for each sample, and the average luminescence value was calculated to determine the anti-hook ability of the product. When the sample is greater than 1000 ng/mL, the highest concentration corresponding to the luminous signal value is taken as the highest concentration that does not produce hook effect of this product.



The test results show that the luminescence value at 1,000-1,000,000 ng/ml increases with the increase of concentration, and no does hook effect appears. Therefore, the maximum analyte concentration of this product without hooking effect is 1,000,000 ng/ml.

• Reference interval

150 serum samples are obtained from a number of healthy people who were not taking medication. The serum samples are all provided by the hospital. Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) is used to analyze the sample based on a single measurement. The nonparametric method was used to establish the reference interval by taking the upper unilateral limit to the 95% percentile.

Based on the experimental results, the reference interval of the product is 0-8.78ng/mL.

• Sample types

180 serum samples and 180 heparin plasma samples from the same individuals are obtained from the hospital. The measurements of serum and plasma are compared and plotted by taking serum results as X-axis and plasma results as Y-axis.

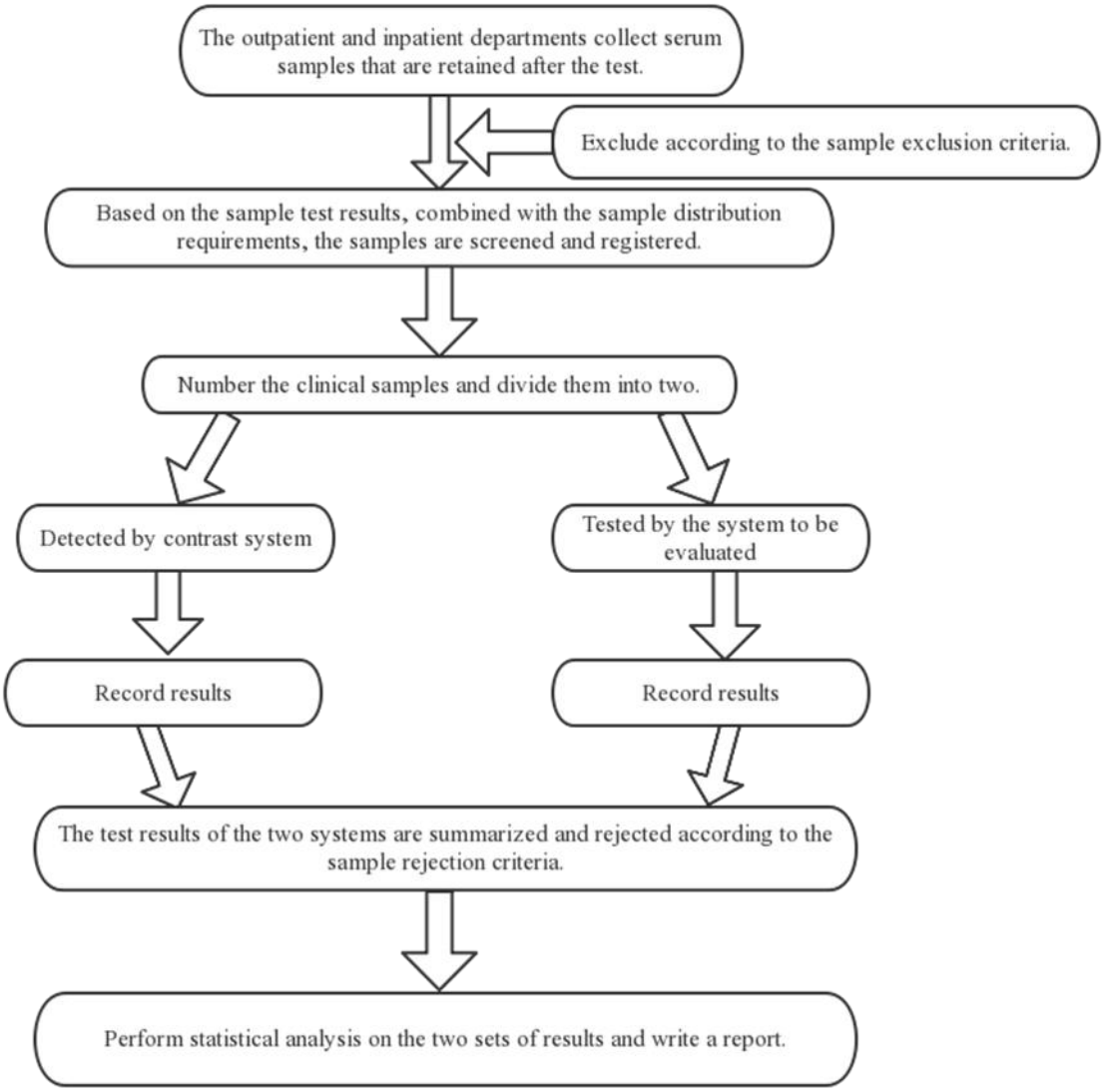
- The correlation coefficient r of the regression equation for the detection results of serum samples and homologous plasma samples is greater than 0.99, then the results of plasma samples of different types of anticoagulants are consistent with those of homologous serum samples.

6.3.2 Summary of Comparison study

The clinical evaluation of the Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) developed by our company was conducted based on the following clinical evidence:

comparison studies between the subject device and the equivalent device, demonstrating that Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) exhibit the same clinical performance with the equivalent device.

The comparison studies between Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) and Elecsys AFP assay(Roche Diagnostics)



Regression analysis and Bland-Altman analysis will be conducted to assess the between-method agreement of the two assays.

150 serum samples were both tested by Elecsys AFP assay (comparative reagent) and Alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA) (evaluation reagent). The data from the test results of the two groups of reagents were analyzed by linear regression and Bland-Altman analysis. The correlation coefficient (r2) of 0.9993 was obtained in the regression analysis, while Bland-

Altman plot confirmed the good between-method agreement by a small average deviation of 1%. The analyses confirmed the evaluation reagent and comparative reagent have high consistency.

The equivalent device has been widely used for AFP quantification to assist in the diagnosis, monitor disease progression, and evaluate the therapeutic effects of HCC. To validate our device, we conducted a clinical study comparing measurements from both assays, demonstrating consistent results. Additionally, we reviewed published literature to gather information on the clinical benefits and performance of the equivalent device. Given the high consistency between our results and those of the equivalent device, we confirmed that our device provides accurate and reliable biomarker quantification, ensuring its subsequent clinical benefit for HCC management.

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6.4 Summary of performance data from other sources

Not applicable

6.5 An overall summary of the performance and safety

The performance of AFP testing in diagnosing hepatocellular carcinoma (HCC) includes high sensitivity in certain contexts, valuable for initial screening and monitoring, particularly when combined with other biomarkers for improved accuracy. However, risks involve variable specificity and potential for false positives or negatives, necessitating careful interpretation. While AFP testing aids in HCC management, its limited prognostic value for survival underlines the importance of comprehensive diagnostic strategies.

6.6 Ongoing or planned post-market performance follow-up

Post-market performance follow-up is planned with the aims of:

a) Confirming the safety and performance of the device throughout its expected lifetime;

b) Identifying previously unknown risks or limits to performance and contraindications;

c) Identifying and analyzing emergent risks based on factual evidence;

d) Ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio referred to in section 1 and 8 of Chapter I of IVDR Annex I;

e) Identifying possible systematic misuse or off-label use of the device, to verify that the intended purpose is correct.

The following table 1 identified the PMPF inputs for alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA).

Table 1 PMPF inputs for alpha-fetoprotein (AFP) Assay Reagent Kit (CMIA)

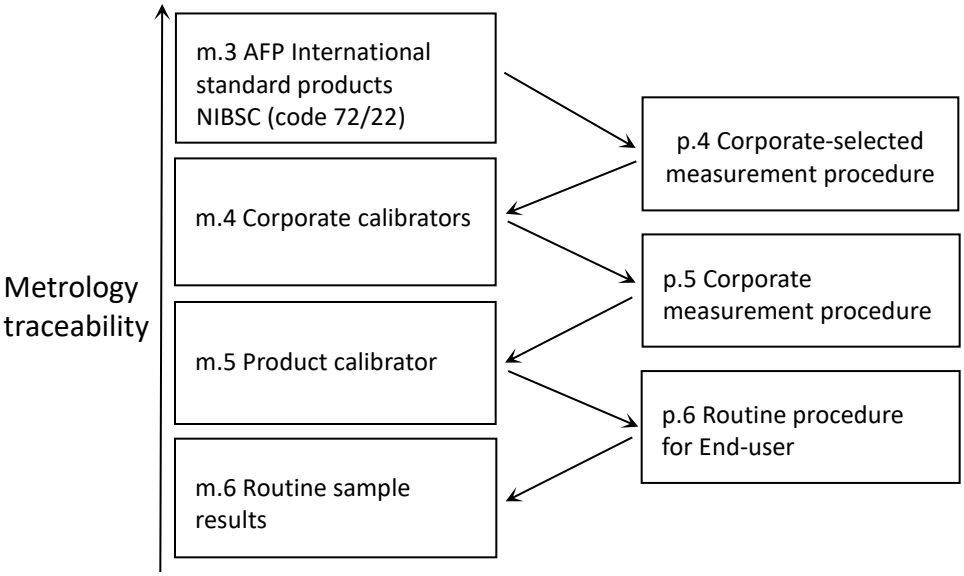
Category	Item #	Description of input	Responsible Dep/person	Frequency of review
General methods and procedure	1	Complaint data (individual complaint records and trend analysis of complaints following company procedure)	QA complaint handling unit	Monthly
	2	Adverse event and recall databases, including information related to the subject device and similar product in the market (e.g., MAUDE: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM MHRA: https://www.gov.uk/drug-device-alerts)	QA regulatory unit	After search completed
	3	Customer satisfaction survey (carry out customer survey according to company procedure requirements)	QA customer service unit	Semi-annual
	4	Scientific literature, including information related to state-of-the-art, device under evaluation and similar device. The databases include PubMed, Cochrane library systematic review, Cochrane Central trials register and clinicaltrials.gov.	Clinical affairs	After search completed

	5	Internal audits and external inspections, including supervisory reviews conducted by third parties or competent authorities as well as the non-specific information checks within the company based on risk arising from medical devices, frequency of medical device non-compliance, or doubts about the quality system	QA regulatory unit	After inspection completed

We think PMPF information can be collected comprehensively through general methods and procedures mentioned above. We think post-market performance study is unnecessary due to below two reasons. 1) The device has been on the market for a considerable period without significant adverse events or safety concerns and has consistently met its performance specifications; 2) Sufficient information can be collected through general methods and procedures listed above; 3) Complaint data and customer satisfactory survey can help us collect valuable information.

7 Metrological traceability for calibration

An AFP calibrator assignment process was established to ensure the accuracy and traceability of the AFP reagents and calibrators used for patient samples. Refer to ISO 17511-2020 for traceability of calibration samples. This product can be traced back to the WHO international standard NIBSC (code: 72/225), and the traceability chain is shown in the following：



AFP traceability chain

The traceability process of a batch of working calibrators and product calibrators is described, and the uncertainty is evaluated. The results are as follows:

Working calibrator	Target value (unit: ng/mL)
S1	1.90 ± 0.0986
S2	9.63 ± 0.4596
S3	47.50 ± 1.6626
S4	236.43 ± 9.2692
S5	957.85 ± 18.1504

Product calibrator	Target value (unit: ng/mL)
C1	4.37 ± 0.6106
C2	418.93 ± 34.0252

8 Suggested profile and training for users

The use-specific limitations in the IFU for the alpha-fetoprotein (AFP) Assay Reagent Kit (MCIA) state: for professional use only.

9 Revision history

SSP Revision Number	Date issued	Change Description	Revision validated by the Notified Body
001	30 Aug 2023	Initial Release	☐Yes Validation language: ☐ No (only applicable for class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB)
002	26 Nov 2024	Part 6 was updated according to MDCG 2022-9, the following were rewritten 6.1Summary of scientific validity of the device 6.2 Summary of performance data from the equivalent device	☐Yes Validation language: ☐ No (only applicable for class C (IVDR, Article 48 (7)) for which the SSP is not yet validated by the NB)