Product Data Sheet - ANCA (Formalin) (IFA)

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Identification of the device

Device Name: Diagnostic Kit for ANCA (Formalin) (IFA)

Specification: 60 Tests/kit; 120 Tests/kit.

Product Code : CK-2204-060G / CK-2204-120G

Intended purpose

For the in vitro qualitative determination of anti-neutrophil cytoplasmic antibodies (ANCA) in human serum.

The kit is used clinically as an aid in the diagnosis of various autoimmune diseases such as primary small vessel vasculitis, inflammatory bowel disease and autoimmune liver disease.

Classification

Others as per IVDD

Class B as per IVDR

Device Description

Principle of operation

Diagnostic Kit for ANCA (Formalin) (IFA) was detected by indirect immunofluorescence assay. The sample is incubated with biological slide coated formalin-fixed human neutrophil. If there is specific antibody in the sample, the antibody will bind specifically to the corresponding antigen in the cell. Then incubate with anti-human IgG labeled with FITC, which reacts with the antibody bound in the cell to present green fluorescence.

The kit can be used manually or instrumently.

Composition

NOTE: Do not mix components from different lots.

Components	Specification	Ingredients

Cells antigen slide	6 Tests/slide ×10; 12 Tests/slide ×10	Formalin-fixed human neutrophil
Conjugate	5.0mL/bottle ×1	Rabbit anti-human IgG labeled with FITC, bovine serum albumin, proclin300.
ANCA-F positive control(P-ANCA)	0.5mL/bottle ×1	Human serum (P-ANCA, diluted), proclin300.
ANCA-F positive control(C-ANCA)	0.5mL/bottle ×1	Human serum (C-ANCA, diluted), proclin300.
ANCA-F negative control	0.5mL/bottle ×1	Human serum (diluted), proclin300.
Buffer	9.57g/bag×4	PBS buffer.
Mounting medium	5.0mL/bottle ×1	PBS buffer, glycerol, proclin300.
Cover slide	60mm×24mm×12	/
IFU	1	/

Performance Index

Appearance and character The components of the kit should be complete, and no liquid leakage. Packaging labels should be clear, accurate and firm. Antigen slide components should be sealed in the sealed bags, no breakage, and no fracture.

Loading quantity It should be no less than the marked loading value of the reagent bottle. The loading quantity of buffer should be in the range of (9.57±0.1g)/bag.

Lowest limit of detection (LOD) LOD ≤ 1:20.

Positive coincidence rate For the detection of corporate positive references, the results should all be positive, the positive coincidence rate should be 100%.

Negative coincidence rate For the detection of corporate negative references, the results should all be negative, the negative coincidence rate should be 100%.

Repeatability For the detection of corporate repeatability references, the fluorescence intensity should be essentially consistent.

Batch-to-batch difference For the detection of corporate repeatability references with 3 batches of kits, the fluorescence intensity should be essentially consistent.

Reference to Previous Device Generation

Not applicable. There is no previous generation of the device.