

**QUALITY ASSURANCE DEPARTMENT****Certificate of Kit Performance****SeroCT™ IgG****Catalog No. A181-01M****Kit No.: E0433100****Expiry Date: 2025-10****1. Description of components**

Components	Code	Quantity	Lot No.	Expiry Date
Plate	181-02	12 Strips	D0264701	2026-02
HRP- Conjugate 300x	A181-12	1 x 0.2 ml	E04333A0	2025-10
Serum Diluent	A180-03	1 x 30 ml	E02120E0	2026-08
Conjugate Diluent	A180-04	1 x 40 ml	E03205C0	2026-09
Wash Buffer x 20	A180-05	1 x 100 ml	E03206A0	2026-03
Negative Control	A181-09	1 x 2.5 ml	E04334A0	2025-10
Positive Control	A181-10	1 x 2.0 ml	E04335A0	2025-10
TMB Substrate	A100-25	1 x 14 ml	E03217E0	2027-06
Stop Solution	A100-14	1 x 15 ml	E03216E0	2027-03
Cover	3211	1		

The control components of this kit contain human sera, which have been tested by FDA and CE approved techniques, and found to be negative for HBV antigen and for HCV and HIV 1&2 antibodies.

2. Control Performance Data

Component	O.D 450 nm	Specification
Positive Control	2.152	> 0.8
Negative Control	0.271	0.1-0.4

Test Number: M421-34**Pass / Fail**



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3. Intra assay Variations (n = 10)

Negative and Positive Sera (n = 10)

Specimen No.	(+) serum OD 0.8-1.6	(-) serum OD 0.1-0.4
1	1.486	0.273
2	1.531	0.291
3	1.365	0.263
4	1.501	0.268
5	1.469	0.274
6	1.336	0.262
7	1.463	0.292
8	1.581	0.275
9	1.424	0.253
10	1.420	0.260
Average	1.458	0.271
SD	0.070	0.012
CV %	4.81	4.49
CV% Specifications	< 10%	< 15%

Test Number: M421-34

Pass / Fail

4. Uniformity of plates CV%

Plates CV% = 9.3
OD=0.6-1.6

Specification ≤ 10% (n=96)

Release Test No: M415-135

Pass / Fail

- Comments: 1. All the components of this kit have been calibrated and tested by lot.
2. Each of the Kit Components were assayed for bacterial growth and found to be Negative.



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5. Panel of sera specimen

Sample No.	Cut off Index	COI Specification
F29	0.296	0.191 - 0.527
F40	0.218	0.168 - 0.448
F143	0.609	0.464 - 0.829
F210	0.321	0.201 - 0.449
H171	0.919	0.754 - 1.634
EC86	2.503	Positive
F181	0.373	0.192 - 0.540
F185	1.000	0.834 - 1.635
F128	0.552	0.258 - 0.604
F264	0.273	0.084 - 0.681
EC42	0.182	0.143 - 0.437
EC6	1.486	Positive
EC9	5.004	Positive
H16	0.325	0.207 - 0.602
H107	0.456	0.240 - 0.667
H24	0.286	0.251 - 0.507
H156	4.608	3.635 - 7.538
H161	0.275	0.149 - 0.408

Test Number: M421-34

Pass / Fail

Kit released by: P.P

Date: 24.06.24

Kit approved by:
QC Manager: \$

Date: 24/06/2024

QA Manager: p.libi Meylikho

Date: 24/06/2024