

CERTIFICATE OF ANALYSIS

HAV IgM CASSETTE

REF 4211240 40 Test X

Cont HAV IgM test device
Disposable specimen droppers

LOT
F1112M2H00B

F1112M2H00B

2-30 °C



2018-11

IVD

PHYSICAL CHARACTERISTICS

| REAGENT | TEST | SPECIFICATIONS | RESULTS |
|----------|------------|------------------|---------|
| CASSETTE | APPEARANCE | COMPACT CASSETTE | PASS |

(PASS / FAILURE)

FUNCTIONALITY TEST

| ANALYSIS | SPECIFICATIONS | TEST RESULTS |
|---|---------------------|----------------|
| Positivity 2 IgM positive samples 1 IgM whole blood positive | All positive | All positive |
| Negativity 20 negative samples | All negative | All negative |
| Precision 10 replicates | Uniformed band | Uniformed band |
| LOD Level 1 | Positive | Positive |
| LOD Level 2 | Positive | Positive |
| LOD Level 3 | Positive / Negative | Negative |
| Flow rate | In 2 minutes | In 2 minutes |
| RESULTS | PASS | |

(PASS / FAILURE)

This lot was tested by test methods described in the manufacturer's package insert.

These results are applicable to this lot and sequential sublots, for which a capital letter have been assigned after the lot number.

This Certificate of Analysis is a computer printout and has therefore not been signed by hand.

| | | |
|--|---------------------------|--|
| This lot meets our specifications and is released for sale | APPROVED | Signed Date of Manufacture, 14 December 2016 Mercè Oriol Quality Control Dept. |
| | (APPROVED / NOT APPROVED) | |

