



Certificate of Analysis

Product name

CONFIRM ANTI-PR (1E2)

Material No.

05277990001

Lot No.

F00428

Date of Manufacturing

2019-03-07

Expiry Date

2021-03-04

Parameter**Result****Unit**Final Acceptance Testing
Breast Carcinoma Tissue

Pass

Nuclear staining is interpreted on tissue that is positive for percent tumor cell staining according to the following approximate percent tumor cell staining criteria:

0-50% cell staining (negative)
51-100% cell staining (positive).

Nuclear staining of test and reference slides must score #3.5 for specific staining with a background (non-specific) intensity of #0.5. The specific staining intensity of the test must be within a 0.5 intensity score of the reference slide for a passing result (Scale 0-4).

The intensity of the negative reagent control slide must be 0.5 or less (Scale 0-4).

Bioburden

Pass

Visible bacterial colonies must be 100 or less CFU/mL

Visual Inspection

Pass

Reagent must be clear, and free of turbidity.

Issue date 2019-03-28

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Parameter**Result****Unit**

Reagent must be free of foreign material and substantially free of intrinsic particulate matter.

This lot meets our specification

Disposition by

Ken Eblen

This certificate is a computer printout and has therefore not been signed by hand.

Issue date 2019-03-28

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