

CERTIFICATE OF ANALYSIS

Product Name: CONFIRM Anti-PR (1E2) Primary Antibody

Ventana REF: 790-2223 & 790-4296

Roche Number: 0527799000 & 05278392001

Batch Number: F10358

Test	Acceptance Criteria	Result
Functional Staining on Breast Carcinoma Tissue	The nuclear staining will be interpreted according to the following approximate percent tumor cell staining criteria: 0-50% cell staining (negative) 51-100% cell staining (positive).	PASS
	The specific stain intensity must also be within 0.5 pt. of the reference batch for a passing result (Scale 0-4+).	PASS
	The background intensity must be within 0.5 of the negative control slide (Scale 0-4+).	PASS
	The intensity of the negative reagent control slide must be 0.5 or less (Scale 0-4+).	PASS
Visual Inspection	Reagent must be free of foreign material and substantially free of particulate matter	PASS
	Reagent must be clear and free of turbidity	PASS
Bioburden	Visible bacterial colonies must be less than or equal to 100 CFU/mL	PASS

This lot met the specifications.

Expiration date: 2018/01/28

Manufacture date: 15/Jan/2016

Ken Eblen



09-FEB-2016

Quality Department

Date