

CERTIFICATE OF ANALYSIS

Product Name: CONFIRM Anti-Ki 67 (30-9) Primary Antibody

Ventana REF: 790-4286

Roche Number: 05278384001

Batch Number: G07946

Test	Acceptance Criteria	Result
Functional Staining on breast carcinoma, normal tonsil, or normal lymph node	The test batch must stain 51% or greater of cells on breast carcinoma, normal tonsil, or normal lymph node tissue	PASS
	The specific stain intensity must also be within 0.5 pt. of the reference batch for a passing result	PASS
	The intensity of the negative reagent control slide must be 0.5 or less	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: 2018/10/28

Manufacture date: 28/Oct/2016

Lucia Romero


Quality Department
Date