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**CERTIFICATE OF ANALYSIS**

Product Name: CINtec p16 Histology

Ventana REF: 705-4713 or 725-4713 or 805-4713 or 825-4713

Roche Number: 06695221001 or 06695230001 or 06695248001 or 06695256001

Batch Number: F07051

Test	Acceptance Criteria	Result
Functional Staining on cervical cancer and tonsil	The test batch must score 3.0 or greater on cervical cancer tissue, 2.0 or greater on the epithelial cells of the tonsil, and 1.0 or greater on the scattered germinal center cells of the tonsil	PASS
	The specific stain intensity must also be within 0.5 pt. of the reference batch for a passing result	PASS
	The background intensity must be within 0.5 of the negative control slide	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: 2017/10/28

Manufacture date: 01/OCT/2015

Ken Eblen

20-OCT-2015

Quality Department

Date