

CERTIFICATE OF ANALYSIS

Product Name: CINtec p16 Histology
 Ventana REF: 825-4713
 Roche Number: 06695256001
 Batch Number: E04415

Test	Acceptance Criteria	Result
Functional Staining on cell line tissue	The CINtec p16 Histology must score 3.0 or greater on cervical carcinoma tissue. The epithelial cells of the tonsil must score 2.0 or greater and the scattered germinal center cells must score 1.0 or greater.	PASS
	Background intensity on both tissues must be within 0.5 of the negative control slide.	PASS
	The specific stain intensities must be within 0.5 pt. of the reference batch.	PASS
Visual Inspection	Reagent must be free of foreign material and substantially free of intrinsic particulate matter	PASS
	Reagent must be clear and free of turbidity	PASS
Bioburden	Visible bacterial colonies must be less than or equal 100 CFU/mL	PASS

This lot met the specifications.

Expiry Date: 2016-06-28

Manufacture Date: 12-JUN-2014

Laura A. Jimenez  16-JUN-2014

Quality Department **Date**