

# Certificate of Analysis

**Product name**

CINtec PLUS Cytology (CE IVD)

**Material No.**

06889565001

**Lot No.**

E06759

**Date of Manufacturing**

2018/04/09

**Expiry Date**

2019/11/30

**Parameter****Result****Unit**Functional Testing  
on three ThinPrep cases

Pass

Dual positive staining must have five or more dual-stained cells with intensity scores of 2 to 3 for both p16 and Ki-67.

The signal intensity scores for p16 and Ki-67 test slides must be within 0.5 intensity points from the intensity of the reference slide from the same case.

Background intensity scores for p16 and Ki-67 test slides must score  $\leq 0.75$ .

Visual Inspection

Pass

Reagent must be clear and free of turbidity

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

This lot meets our specification

**Disposition by**

KEN ROCHIN

**Issue date**

10-MAY-2018