

Summary of Safety and Effectiveness

NCY - 5 1996

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitter Information

Contact person: Thomas F. Flynn

Address: Ciba Corning Diagnostics Corp.  
63 North Street  
Medfield, MA 02052

Phone: (508) 359-3877  
FAX: (508) 359-3885  
e-mail: thomas.flynn@cibadiag.com

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2. Device Information

Proprietary Name: ACS Cortisol Immunoassay  
Common Name: Cortisol Immunoassay  
Classification Name: Class II, Cortisol Test System  
21 CFR 862.1205

3. Predicate Device Information

Name: Tdx® Cortisol Fluorescence Polarization Immunoassay  
Manufacturer: Abbott Laboratories  
510(k) Number: Not Known

Name: COAT-A-COUNT Cortisol Radioimmunoassay  
Manufacturer: Diagnostic Products Corporation  
510(k) Number: Not Known

4. Device Description

The Ciba Corning ACS Cortisol assay is a competitive chemiluminescent immunoassay. Cortisol in the patient sample competes with the acridinium ester (AE-labeled cortisol (Lite Reagent) for binding to polyclonal rabbit anti-cortisol antibody on the Solid Phase. The polyclonal rabbit anti-cortisol antibody is bound to monoclonal mouse anti-rabbit antibody, which is coupled to paramagnetic particles (solid phase). An inverse relationship exists between the amount of cortisol present in the patient sample and the amount of relative light units (RLUs) detected by the ACS:180® system.

K962559

**5. Statement of Intended Use**

For the quantitative determination of cortisol in serum using the Ciba Corning Automated Chemiluminescence Systems.

**6. Summary of Technological Characteristics**

The Ciba Corning ACS Cortisol procedure is a competitive chemiluminescent immunoassay.

**7. Performance Data**

**Sensitivity**

The ACS Cortisol immunoassay measures cortisol concentration up to 75 µg/mL with a minimum detectable concentration of 0.20 µg/mL.

**Accuracy**

For 100 extracted urine samples in the range of 8.0 to 148.8 µg/24 hours, the correlation between the ACS Cortisol and the fluorescence polarization immunoassay (FPIA) method is described by the equation:

$$\text{ACS Cortisol} = 0.92 (\text{FPIA}) + 4.8$$

$$\text{Correlation coefficient (r)} = 0.92$$

For 70 extracted urine samples in the range of 13.4 to 175.1 µg/24 hours, the correlation between the ACS Cortisol immunoassay and the Radioimmunoassay (RIA) method is described by the equation:

$$\text{ACS Cortisol} = 1.04 (\text{RIA}) - 1.2$$

$$\text{Correlation coefficient (r)} = 0.96$$