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**AUG 23 1996**

**510(k) Summary of Safety and Effectiveness for  
OPUS hLH**

**1. Manufacturer Name, Address, phone number, contact name and date of preparation.**

Manufacturer: Behring Diagnostics Inc.  
151 University Ave  
Westwood, MA 02090  
617-320-3000  
Contact name: Ruth C. Forstadt

Date of preparation: July 22, 1996

**2. Device Name/Classification**

OPUS hLH Reagents for hLH assay

Classification number: Class II (862.1485)

**3. Identification of the legally marketed device to which the submitter claims equivalence.**

Abbott IMX LH test system

**4. Proposed Device Description**

OPUS hLH is based on the principle of sandwich binding immunoassay. Each test module contains a solid phase anti-LH polyclonal antibody immobilized onto glass fiber. An anti-LH monoclonal antibody/alkaline phosphatase conjugate solution and a wash/substrate solution (4-methylumbelliferylphosphate) are sealed in separate wells within the test module.

**5. Proposed Device Intended Use**

OPUS hLH is a fluorogenic enzyme assay for use with the OPUS analyzers used in the quantitative measurement of lutenizing hormone (LH) in serum or plasma.

**6. Medical device to which equivalence is claimed and comparison information:**

The OPUS hLH test system is substantially equivalent in intended use to the Abbott IMX LH test system. Both products are *in vitro* diagnostic test systems intended for use as a quantitative measurement of human lutenizing hormone (LH) in serum or plasma. The Abbott IMX LH, like the proposed product, employs the principle of two site or sandwich

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immunoassay. Both methods use a labeled antibody for the quantitative measurement of lutenizing hormone (LH) in human serum or plasma. The OPUS hLH and Abbott IMX LH are both based on a six level calibrator system.

The OPUS hLH differs from the Abbott IMX LH in that the solid phase capture antibody is a mouse monoclonal in the Abbott test, while the solid phase capture antibody is a rabbit monoclonal in the OPUS test. Also, the Abbott IMX LH includes a tri-level control, where as the OPUS hLH test system does not include a control.

## **7. Proposed Device Performance Characteristics**

Precision of the OPUS hLH test system was evaluated on an OPUS Immunoassay System. Intra-assay precision was determined by the evaluation of three serum pools in replicates of 20 each. %CV's ranged from 4.56% to 6.32%.

Inter-assay precision was determined by the evaluation of three levels of two sets of control sera assayed in triplicate twice a day for five days for a total of thirty replicates. %CV's ranged from 4.55% to 5.64%.

No interference was detected by levels of TSH up to 1,000 mIU/L, FSH up to 1,000 mIU/ml and Prolactin up to 1,000 ng/ml when evaluated using OPUS hLH. hCG at levels up to 50,000 mIU/ml and hGH at levels up to 1,000 ng/ml showed less than 0.6% crossreactivity with the OPUS LH assay.

### **Accuracy by Correlation**

OPUS hLH was compared to a commercially available immunoassay by evaluation of 143 serum samples ranging from 0.79-109 mIU/ml. A correlation coefficient of 0.98 was obtained with a y-intercept value of 1.06 and a slope of 1.06.

### **Accuracy by Recovery**

Recovery was determined by adding LH at different concentrations to a normal human serum pool with a known endogenous LH concentration. The samples were assayed using OPUS hLH in replicates of three. Percent recovery ranged from 95.3% to 98.1%.

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