K964765

Summary of Safety and Effectiveness

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

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1. Submitters Information

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2. Device Information

Proprietary Name: Chiron Diagnostics ACS:180 Carbamazepine Assay
Common Name: Assay for Carbamazepine

3. Predicate Device Information

Name: TDx® Carbamazepine Assay.

Manufacturer: Abbott Laboratories

4. Device Description

Therapeutic drug monitoring of carbamazepine helps the physician to establish the therapeutic dose based on individual response to the drug, to adjust dosage to reduce adverse effects while controlling seizures, and to ensure patient compliance with the established regimen.

The Chiron Diagnostics ACS:180 Carbamazepine assay is a competitive immunoassay using direct chemiluminescent technology. Carbamazepine in the patient sample competes with an acridinium ester-labeled carbamazepine derivative in the Lite Reagent for a limited amount of monoclonal mouse anti-carbamazepine antibody, which is coupled to paramagnetic particles in the Solid Phase. An inverse relationship exists between the amount of carbamazepine present in the patient sample and the amount of relative light units (RLUs) detected by the system.

5. **Statement of Intended Use**

For the quantitative determination of carbamazepine in serum or plasma using the Chiron Diagnostics ACS:180® Automated Chemiluminescence Systems.

6. **Summary of Technological Characteristics**

The Chiron Diagnostics ACS:180 Carbamazepine assay is a competitive immunoassay using direct chemiluminescent technology.

7. **Performance Characteristics**

Expected Results

A therapeutic range of 4 to 10 µg/mL (16.9 to 42.3 µmol/L) has been previously reported for carbamazepine. As with all therapeutic drug assays, each laboratory should determine the appropriateness of this range for the diagnostic evaluation of patient results.

Sensitivity

The ACS:180 Carbamazepine assay measures carbamazepine concentrations to 20 µg/mL 84.6 µmol/L) with a minimum detectable concentration of 0.2 µg/mL (0.8 µmol/L). Sensitivity is defined as the concentration of carbamazepine that corresponds to the RLUs that are two standard deviations less than the mean RLUs of 27 replicate determinations of the carbamazepine zero standard.

Assay Reportable Range

The ACS:180 Carbamazepine assay measures carbamazepine concentrations up to 20 µg/mL (84.6 µmol/L) with a minimum detectable concentration of 0.2 µg/mL (0.8 µmol/L).

Method Comparison

For 303 samples in the range of 0.87 to 14.06 µg/mL (3.68 to 59.47 µmol/L), the relationship between the ACS:180 Carbamazepine assay and an alternate fluorescence polarization method is described by the equation:

ACS:180 Carbamazepine = 1.01 (alternate method) + 0.71 µg/mL
Correlation coefficient (r) = 0.96

Precision

Six samples were assayed 6 times in 6 assays, on each of 4 systems (n = 144 for each sample), over a period of 3 days. The following results were obtained:

Total precision (%CV) ranged from 5.4 to 6.70