

K960913

## APPENDIX D - Summary of Safety and Effectiveness Information

### 1. General Information

Device Generic Name: Enzyme Immunoassay, Free T3  
Device Trade Name: ACCESS® Free T3 assay  
Applicant's Name and Address: Sanofi Diagnostics Pasteur, Inc.  
1000 Lake Hazeltine Drive  
Chaska, MN 55318  
(612) 448 - 4848  
Contact: Katia Breslawec

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### 2. Predicate Device

Magic® 1-Free T3 Radioimmunoassay  
Ciba Corning Diagnostics Corporation  
63 North Street  
Medfield, MA 02052

### 3. Device Description

The ACCESS® Free T3 reagents and the ACCESS® Immunoassay Analyzer comprise the ACCESS® Immunoassay System for the quantitative determination of free triiodothyronine in human serum.

### 4. Indications for Use

The ACCESS® Free T3 assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of free triiodothyronine levels in human serum using the ACCESS® Immunoassay System. The ACCESS® Free T3 assay aids in the diagnosis of hyperthyroidism.

### 5. Comparison of Technological Characteristics

The ACCESS® Free T3 assay and the Ciba Corning Magic® 1-Free T3 assay are intended for the measurement of free triiodothyronine in human serum. The ACCESS® Free T3 assay and the Ciba Corning Magic® 1-Free T3 assay use multi-point calibrators/standards prepared in human serum. The ACCESS® Free T3 assay is non isotopic and uses a dioxetane based chemiluminescent substrate, while the Ciba Corning Magic® 1-Free T3 assay is a radioimmunoassay utilizing <sup>125</sup>I labeled triiodothyronine. The ACCESS® Free T3 assay measures light production from a chemiluminescent reaction, while the Ciba Corning Magic® 1-Free T3 assay measures radioactivity. The ACCESS® Free T3 assay binds polyclonal capture antibody to paramagnetic particles, while the Ciba Corning Magic® 1-Free T3 assay binds polyclonal anti-T3 to microparticles. The ACCESS® Free T3 assay is a two step competitive binding immunoassay, while the Ciba Corning Magic® 1-Free T3 assay is a one step competitive immunoassay.

### 6. Summary of Studies

Precision studies: Within run precision ranges from 3.74% CV (high control) to 12.75% CV (low control). Total imprecision ranges from 5.08 % CV (high control) to 13.42 % CV (low control).  
Correlation: A comparison of Free T3 values from 217 samples run in both the ACCESS® Free T3 assay and the Ciba Corning Magic® 1-Free T3 assay test gives the following statistical data:  $r = 0.929$ ,  $y = -1.09 + 1.33x$ .  
Analytical Sensitivity: The lowest detectable level of Free T3 distinguishable from zero (Free T3 Calibrator S0) with 95% confidence is 0.30 pg/ml.

### 7. Conclusion

The ACCESS® Free T3 reagents when used with the ACCESS® Immunoassay Analyzer are substantially equivalent to another test for the measurement of Free T3 currently in commercial distribution.