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## APPENDIX D - Summary of Safety and Effectiveness Information

1. **General Information** — January 13, 1997

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|---|---|
| Device Generic Name: | Enzyme Immunoassay, Estradiol |
| Device Trade Name: | ACCESS® Estradiol assay |
| Applicant's Name and Address: | Sanofi Diagnostics Pasteur, Inc.<br>1000 Lake Hazeltine Drive<br>Chaska, MN 55318 |

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2. **Predicate Device**
Abbott IMx® Estradiol Kit
Abbott Laboratories
Diagnostics Division
Abbott Park, IL 94547

3. **Device Description**
The ACCESS® Estradiol reagents and the ACCESS® Immunoassay Analyzer comprise the ACCESS® Immunoassay System for the quantitative determination of Estradiol levels in human serum.

4. **Indications for Use**
The ACCESS® Estradiol assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of Estradiol levels in human serum using the ACCESS® Immunoassay System.

5. **Comparison of Technological Characteristics**
The ACCESS® Estradiol assay and the Abbott IMx® Estradiol Kit are for the measurement of estradiol in human serum. Both tests utilize polyclonal rabbit anti-estradiol antibodies for capture and an alkaline phosphatase conjugate. Both tests use multi-point liquid calibrators. The ACCESS® Estradiol assay uses a dioxetane based chemiluminescent substrate while the Abbott IMx® Estradiol Kit uses 4-methylumbelliferyl phosphate as the substrate. The ACCESS® Estradiol assay measures light production from a chemiluminescent reaction, while the Abbott IMx® Estradiol Kit measures a fluorescent product. The ACCESS® Estradiol assay uses calibrators prepared in a human serum matrix while the Abbott IMx® Estradiol Kit uses calibrators prepared in Tris buffer with protein stabilizers. The ACCESS® Estradiol assay uses a simultaneous assay format while the Abbott IMx® Estradiol Kit uses a sequential assay format.

6. **Summary of Studies**
Precision studies: Within run precision ranges from 11.6% CV (117 pg/ml) to 2.7% CV (3041 pg/ml). Total imprecision ranges from 21.1% CV (72 pg/ml) to 5.2% CV (1456 pg/ml).
Accuracy: Spiking recovery studies performed by spiking estradiol into ten serum samples results in recovery ranging from 92% to 106%. Dilution recovery studies performed by diluting 18 patient samples containing estradiol 1:2 with Estradiol Calibrator S0 results in a mean recovery of 105% with a standard deviation of 7%.
Correlation: A comparison of estradiol values from 214 samples run in both the ACCESS® Estradiol assay and the Abbott IMx® Estradiol Kit test gives the following statistical data: $r = 0.958$, $y = -39 + 0.983x$.
Analytical Sensitivity: The lowest detectable level of estradiol distinguishable from zero (Estradiol Calibrator S0) with 95% confidence is 23 pg/ml.
Analytical Specificity: Estrone sulfate is not detectable when spiked into the S0 calibrator at 3600 pg/ml. Estriol sulfate gives an apparent cross reactivity of 0.04% when spiked into the S0 calibrator at 10,000,000 pg/ml.

7. **Conclusion**
The ACCESS® Estradiol reagents when used with the ACCESS® Immunoassay Analyzer are substantially equivalent to another test for the measurement of estradiol levels now in commercial distribution.