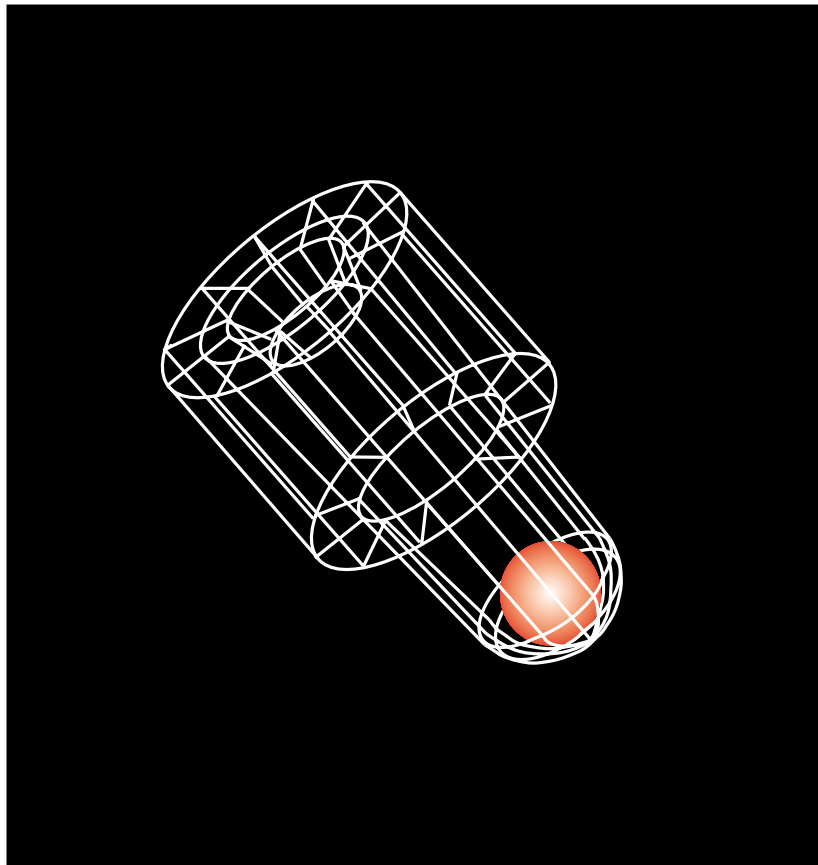


Negligible HCG Carryover on the IMMULITE® and IMMULITE® 2000

*Esther Reichstein, PhD
Director, Immunochemistry and
Technical Support
DPC Cirrus, Randolph, NJ*

*Marie Knapick, BS, MT (ASCP)
Associate Scientist
DPC Cirrus, Randolph, NJ*



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Introduction

Positive liquid displacement pipetting probes are superior to disposable tips in both reliability and cost. Superior design and appropriate maintenance can ensure that reusable probes also exhibit little or no carryover. DPC Cirrus probes are designed to have excellent precision and very low carryover. Studies with samples assayed for human chorionic gonadotropin (HCG) have shown that an IMMULITE or IMMULITE 2000 probe cleaned daily with the appropriate DPC Probe Cleaning Kit will have low carryover for the life of the probe.

Methods

The IMMULITE HCG (LKCG) and IMMULITE 2000 HCG (LKCG) chemiluminescent enzyme immunometric assays both have a calibration range of up to 5,000 mIU/mL (WHO 3rd IS 75/537). IMMULITE HCG has an analytical sensitivity of 1.1 mIU/mL; IMMULITE 2000 HCG has an analytical sensitivity of 0.4 mIU/mL.

In the study outlined here, HCG samples (third-trimester pregnancy samples or male teratoma or seminoma samples) with concentrations ranging from 20,000 to just under 2,000,000 mIU/mL were used to test for carryover on both the IMMULITE and the IMMULITE 2000 immunoassay analyzers. The probes ranged in age from one month to two years. All probes had been maintained by daily cleaning with DPC's IMMULITE (LKPM) or IMMULITE 2000 (L2KPM) Probe Cleaning Kit as recommended by DPC.

The HCG concentration of each sample was determined by assaying 100- to 500-fold dilutions of the sample. Carryover was tested by assaying one replicate of the undiluted sample followed by four replicates of DPC's HCG Sample Diluent. Two to four carryover measurements were made on each instrument type with multiple instruments. A measurable dose in the first "zero" sample following the undiluted sample was indicative of sample carryover.

Results

The carryover ranged from nondetectable to a maximum of 6 ppm, even for samples with the highest concentrations.

Table 1. HCG result ranges in first zero samples following undiluted pregnancy samples, mIU/mL.

Sample	IMMULITE	IMMULITE 2000
22,000	ND	ND
33,300	ND	ND
45,500	ND	ND
51,300	ND	ND
57,400	ND	ND
84,600	ND to 2.3	ND
85,100	ND	ND
97,800	ND	ND
103,000	ND	ND
150,000	ND to 1.2	ND

ND = nondetectable

Table 2. HCG result ranges in first zero samples following undiluted male teratoma and seminoma samples, mIU/mL.

Sample	IMMULITE	IMMULITE 2000
109,740	ND	ND
156,540	ND	ND
359,980	1.8 to 1.9	ND
387,370	ND	ND
588,000	ND	ND to 1.5
565,000	ND	ND to 1.6
1,270,000	ND to 2.8	ND to 5.9
1,750,000	2.0 to 10.8	3.3 to 9.8

ND = nondetectable

Conclusion

This study demonstrates that a well-maintained probe may exhibit minimal carryover.



Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597
Tel: 800.372.1782
Tel: 310.645.8200
Fax: 310.645.9999
E-Mail: info@dpconline.com
Web site: www.dpcweb.com