



REPUBLIC OF THE PHILIPPINES  
**DEPARTMENT OF HEALTH**  
**BUREAU OF FOOD AND DRUGS**

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NA PAMAYANAN

04 August 2006

**Ms. BERNARDA J. SURATOS**  
Company Pharmacist  
**Medical Trends & Technologies, Inc.**  
200 J. Elizalde St., Phase V  
B.F. Homes, Parañaque City

Subject: Advanced HCV Elisa Test Kit  
RSN 05G-31

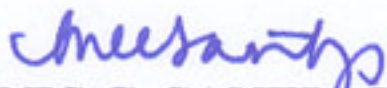
Dear **Ms. Suratós**,

This is with reference to your letter dated 19 July 2006 requesting for a copy of the Assay Evaluation Report done on the above subject product.

We are enclosing herewith six (6) pages summary of evaluation report performed by National Reference Laboratory - STD/AIDS Cooperative Central Laboratory (NRL/SACCL).

For your information and guidance.

Very truly yours,

  
**MA. LOURDES C. SANTIAGO, MSc,MM**  
OIC, Product Services Division

Ref# 06-5107  
RRS/CAB

**AUG 1 0 2006**

**SUMMARY OF EVALUATION**

(May' 2006)

Name of Test Kit : Advanced HCV EIA  
BFAD Reference No. 05G-31(Initial)

Manufacturer : Intec Products Inc, China

Distributor : Medical Trends & Technologies, Inc

Number of Test Kits Submitted : 9 x 96T

Lot Numbers : 2005071902(A); 2005071202(B)

Expiry Date : 7/19/06; 7/12/06

Date of Analysis : April'2006

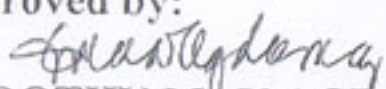
Results :

Sensitivity%(95CI)	98.08% (92.5-99.7)
Specificity%(95CI)	100% (98.8-100)
Reproducibility %	100%
Test Efficiency %	99.61%

Recommendation : **RECOMMENDED FOR BFAD REGISTRATION**

**RECOMMENDING APPROVAL OF TECHNICAL EVALUATION RESULTS:**

Approved by:

  
DOROTHY MAY AGDAMAG, MD, FPSP, MSc

Head, NRL-SACCL  


## ASSAY EVALUATION REPORT

### I. GENERAL CHARACTERISTIC

Name of test kit : Advanced HCV EIA

Assay Type : Enzyme Linked Immunosorbent Assay

Antigen/Antibody Type : Recombinant

Solid Phase : microwell plate

Number of Test per Kit : 96 tests/kit

Date of Kit Submitted for Evaluation : February, 2006

Lot Numbers (1-2) : 200571902(A), 2005071202(B)

Expiry Dates : 7/19/06; 7/12/06

Shelf-life ( $^{\circ}\text{C}$ ) : 2-8 $^{\circ}\text{C}$ , up to expiration date

Volume of serum needed (ul) : 10 ul

Final dilution of Serum : 1:10

Total Time to Perform the Assay (h.min.) : 2.0

Wavelength (nm) single : 450; 450/630

Test Procedure Used : semi- automated

### II. OPERATIONAL ASPECT

Storage Condition ( $^{\circ}\text{C}$ ) : 2-8  $^{\circ}\text{C}$

Incubation Temperature : 37 $^{\circ}\text{C}$