



United States  
Department of  
Agriculture

September 21, 2011

Animal and Plant  
Health Inspection  
Service

Veterinary Services

MD/DE/DC Area  
Office

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Annapolis, MD 21409

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Dear STRATEGIC DIAGNOSTICS, INC. D/B/A SDIX:

The following facility was inspected on 8/23/2011 for compliance with Regulation (EC) 1069/2009 and Regulation (EU) 142/2011:

STRATEGIC DIAGNOSTICS, INC. D/B/A SDIX  
128 Sandy Drive  
Newark, Delaware, 19713

The facility has been approved by APHIS to conduct the following activities related to Regulation (EC) 1069/2009 and Regulation (EU) 142/2011:

#### TWO APPROVALS

APPROVAL ONE: APHIS DOES NOT ENDORSE ANY DOCUMENTS BASED UPON THIS APPROVAL. THIS APPROVAL IS NOT FOR ANY OTHER PURPOSE OTHER THAN TO VERIFY THAT THE FACILITY IS:

APPROVED TO SHIP INTERMEDIATE PRODUCTS TO THE EU ACCOMPANIED BY THE REGULATION (EU) 142/2011 CHAPTER 20 'DECLARATION FOR THE IMPORT FROM THIRD COUNTRIES AND FOR THE TRANSIT THROUGH THE EUROPEAN UNION OF INTERMEDIATE PRODUCTS TO BE USED FOR THE MANUFACTURE OF MEDICINAL PRODUCTS, VETERINARY MEDICINAL PRODUCTS, MEDICAL DEVICES, IN VITRO DIAGNOSTICS AND LABORATORY REAGENTS' SIGNED BY THE EU IMPORTER.

APPROVAL TWO: APPROVED UNDER 142/2011 AS A TECHNICAL BLOOD (OTHER THAN EQUIDAE) FACILITY TO:

1. SUPPLY THE FOLLOWING UNTREATED BLOOD PRODUCTS TO US FACILITIES FOR EVENTUAL EXPORT TO THE EU.
  - GOAT/CAPRA HIRCUS SERA, ANTIBODIES
  - SHEEP/OVIS ARIES SERA, ANTIBODIES
  - RABBIT/ORYCTOLAGUS CUNICULUS SERA, ANTIBODIES
2. EXPORT THE FOLLOWING UNTREATED BLOOD PRODUCTS TO THE EU ON THE 4C. (RUMINANT AND PORCINE PRODUCTS MUST BE SHIPPED DIRECTLY TO AN EU APPROVED ESTABLISHMENT.)
  - GOAT/CAPRA HIRCUS SERA, ANTIBODIES
  - SHEEP/OVIS ARIES SERA, ANTIBODIES
  - RABBIT/ORYCTOLAGUS CUNICULUS SERA, ANTIBODIES



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3. PERFORM THE FOLLOWING ACTIVITIES RELATED TO “PERITONEAL FLUID COMMODITIES”. ALL DOCUMENTS/CERTIFICATES RELATED TO THESE COMMODITIES MUST CLEARLY IDENTIFY THE COMMODITIES AS “PERITONEAL FLUID” IN ORIGIN.

- COLLECT PERITONEAL FLUID ONSITE FROM THE FOLLOWING LIVE ANIMALS: MOUSE/MUS MUSCULUS

- SUPPLY THE FOLLOWING PERITONEAL FLUID PRODUCTS TO US FACILITIES FOR EVENTUAL EXPORT AT THE SHIPPER’S OWN RISK TO THE EU: MOUSE/MUS MUSCULUS ASCITES, ANTIBODIES FORM ACITES

-EXPORT THE FOLLOWING PERITONEAL FLUID PRODUCTS AT THE SHIPPER’S OWN RISK TO THE EU ON THE 4C (4C MAY NOT BE ENDORSED FOR CONSIGNMENTS TO EU COUNTRIES WHERE THE COUNTRY-SPECIFIC IREGS SPECIFICALLY INDICATE THAT PERITONEAL FLUID PRODUCTS MAY NOT BE EXPORTED ON THE CHAPTER 4 CERTIFICATES) : MOUSE/MUS MUSCULUS ASCITES, ANTIBODIES FROM ASCITES

The facility has been granted APHIS Reference Number DE-TEC-0001. This number may not be utilized to indicate that APHIS has approved the facility or products for other purposes.

In order to retain this approval, the facility must continue to operate under the information provided during the approval process. The facility is subject to unannounced compliance inspections throughout the year to verify this continued compliance.

Lastly, I would like to remind you that the facility must complete the renewal process no later than 8/23/2012. Please contact this office no later than two months prior to this date to initiate the re-approval process.

Please let me know if you have any questions or concerns.

Sincerely,

Kent Holm  
Veterinary Medical Officer