



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

AUG 30 2004

400 Seventh St., S.W.
Washington, D.C. 20590

Ellis Jacobs, Ph.D., DABCC
Director, Clinical Laboratory
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Wadsworth Center
New York State Department of Health
P.O. Box 509
Albany, NY 12201-0509

Reference No. 03-0113

Dear Dr. Jacobs:

This is in response to your letter asking if whole blood samples offered for transportation by your program to administer various proficiency tests for the purpose of licensing laboratories in the State of New York are subject to the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). From telephone conversations with Ms. Kathi Wagner of your staff, we understand the whole blood has been tested and determined to not meet the definition of a hazardous material, but before being offered for commercial transportation to the laboratories for analysis, various chemicals, parasites, or microbiological agents may be added. We apologize for the delay in responding and any inconvenience this may have caused.

You are correct that blood collected for transfusion and biological products subject to approval by the Food and Drug Administration or the U.S. Department of Agriculture are not subject to the HMR (see § 173.134(b)). However, the samples you use for your various test programs may be subject to the HMR if you add chemicals or other materials to the samples.

Blood and other biological samples that do not meet the definition of a Division 6.2 (infectious) material in § 173.134(a) or the definition of another class of hazardous material in Part 173 are not subject to the HMR. Thus, the blood samples you transport for your engraftment monitoring, immunohematology proficiency test, and parentage/identity testing programs are not regulated under the HMR. Similarly, if the serum samples you transport for your clinical chemistry, cytokines, diagnostic immunology, endocrinology, hematology, oncology, parasitology, therapeutic substance monitoring, and clinical and toxicology proficiency test programs are not infectious and do not meet the definition of another hazard class, they are not subject to the HMR.

Sincerely,

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Standards



040113

173.134 (4)



STATE OF NEW YORK
DEPARTMENT OF HEALTH

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Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

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Executive Deputy Commissioner

5/8/03

Edmonson
§ 173.134 (4)
Diagnostic Specimen
03-0113

April 3, 2003

Ryan Posten
US Department of Transportation
Research and Special Programs Administration/DHM31
400 7th Street SW
Washington, DC 20590

Dear Mr. Posten:

The Clinical Laboratory Evaluation Program (CLEP) of the Wadsworth Center, New York State Department of Health licenses laboratories conducting testing on any specimens originating in New York State. As part of the licensure program, CLEP administers proficiency testing to the approximately 950 clinical laboratories participating in the program. Proficiency tests for each category required by state and federal regulations are submitted to participating laboratories three times per year, except for testing in Urinalysis, Mycobacteriology, and Parentage/Identity Testing, which occur twice per year.

We would like to confirm our understanding of the new shipping regulations as they relate to our proficiency testing program.

According to Section 173.134(b)(4) blood collected for the purpose of blood transfusion are not subject to the requirements of this subchapter as Division 6.2 materials. The Engraftment Monitoring, Immunohematology and Parentage/Identity Testing proficiency testing programs prepare their proficiency testing samples from whole blood collected by a licensed blood center. Therefore, we would like to confirm that these four programs are exempt from the packing requirements for diagnostic specimens.

Engraftment Monitoring

This program purchases whole blood from the Red Cross. The blood is tested and found negative for HBsAg, anti-HBc, anti-HIV-1, anti-HIV-2, anti-HCV and anti-HTLV-I, ALT, syphilis and NAT for HIV and HCV. Wadsworth Center staff dispenses the whole blood into plastic cryotubes.

Approximately 10 laboratories participate in the bone marrow engraftment monitoring proficiency testing program that is administered twice a year.

Immunohematology Proficiency Test

The proficiency test consists of five whole blood samples and five lyophilized serum samples.

The Immunohematology program purchases whole blood from the Red Cross from their inventory of blood collected for transfusion. The blood is tested and found negative for HBsAg, anti-HBc, anti-HIV-1, anti-HIV-2, anti-HCV and anti-HTLV-I, ALT, syphilis and NAT for HIV and HCV and meets all requirements for transfusable blood. Two mL of whole blood is dispensed into sterile serum vials, capped with a rubber stopper and metal seal.

The serum samples are purchased from reagent manufacturers and have been tested for anti-HIV-1, anti-HIV-2, HIV-1 p24 antigen, anti-HCV, HBsAg and syphilis. Wadsworth Center staff dilutes the serum in varying concentrations. Three mLs of the diluted serum is dispensed into sterile serum vials, lyophilized, and capped with a rubber stopper and metal seal.

Approximately 350 laboratories participate in the Immunohematology proficiency testing program that is administered three times per year.

Parentage/Identity Testing

This program purchases whole blood from the Red Cross. The blood is tested and found negative for HBsAg, anti-HBc, anti-HIV-1, anti-HIV-2, anti-HCV and anti-HTLV-I, ALT, syphilis and NAT for HIV and HCV. Wadsworth Center staff dispenses the whole blood into plastic cryotubes.

Approximately 25 laboratories participate in the paternity/identity proficiency testing program that is administered twice a year.

According to Section 173.134(b)(3), biological products are not subject to the requirements of this subchapter as Division 6.2 materials. The following proficiency testing programs prepare their proficiency testing samples from materials purchased from a licensed manufacturer. Therefore, we would like to confirm that these programs are exempt from the packing requirements for diagnostic specimens.

Clinical Chemistry Proficiency Test

The proficiency samples are prepared from bulk serum that is purchased from a licensed manufacturer. The bulk serum has been tested and found negative for HBsAg, anti-HIV-1, anti-HIV-2, HIV-1 antigen and anti-HCV and the results of this testing are provided by the manufacturer.

The Wadsworth Center staff adds the analytes (alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, total bilirubin, total calcium, chloride, total cholesterol, HDL Cholesterol, LDL Cholesterol, creatine kinase, creatine kinase-MB, creatinine, gamma glutamyltransferase, glucose, homocysteine, iron, lactate dehydrogenase, lactate dehydrogenase isoenzyme 1, magnesium, phosphorus, potassium, sodium, total protein, Triglycerides, urea nitrogen and uric acid) to the bulk serum in varying concentrations.

The serum is then sterile filtered and dispensed in six mL aliquots into individual glass serum vials. The vials are capped with a rubber stopper and metal seal and stored frozen.

Approximately 470 laboratories participate in the clinical chemistry proficiency testing program that is administered three times per year. Five serum vials are sent to each laboratory enrolled in the NYS proficiency testing program for evaluation.

Cytokines Proficiency Test

The proficiency samples are prepared from bulk serum that is purchased from a licensed manufacturer. The bulk serum has been tested and found negative for HBsAg, anti-HIV-1, anti-HIV-2, HIV-1 antigen and anti-HCV and the results of this testing are provided by the manufacturer.

The Wadsworth Center staff adds the analytes (INF-gamma, IL-2, IL-6, TNF-alpha) to the bulk serum in varying concentrations.

The serum is dispensed in three mL aliquots into individual 12X75 plastic tubes with a snap cap. The vials are also covered with parafilm and stored frozen.

Approximately 10 laboratories participate in the proficiency testing program for cytokines that is administered three times per year. Three serum vials are sent to each laboratory enrolled in the NYS program for evaluation.

Diagnostic Immunology Proficiency Test

The proficiency samples are prepared from bulk serum purchased from a licensed manufacturer. The certificate of analysis provided by the manufacturers indicates the various concentration of the analytes (IgA, IgG, IgM, IgE, C3, C4, heterophile, rubella antibody, alpha-1 antitrypsin, antinuclear antibody, antistreptolysin O, anti-CMV, rheumatoid factor, syphilis reagin, syphilis treponemal antibody and lyme disease antibody) and that the bulk serum tested negative for HBsAg, anti-HIV-1 and anti-HTLV-I/II. Bulk serum is dispensed under sterile conditions in 0.3 mL to 3.0 mL aliquots into labeled plastic vials, capped and shipped liquid with identification as to contents. Up to sixteen sets containing five serum vials each are sent to laboratories enrolled in the NYS program for evaluation. Approximately 450 laboratories participate in the diagnostic immunology proficiency testing program that is administered three times per year.

Endocrinology Proficiency Test

The proficiency samples are prepared from bulk serum that is purchased from a licensed manufacturer. The bulk serum has been tested and found negative for HBsAg, anti-HIV-1, anti-HIV-2, HIV-1 antigen and anti-HCV and the results of the testing are provided by the manufacturer.

The Wadsworth Center staff adds different hormones (e.g. cortisol, estradiol, folic acid, estriol, follicle stimulating hormone, human chorionic gonadotropin, insulin, luteinizing hormone, testosterone, triiodothyronine (T3), Thyroxin (T4), Thyroid Stimulating Hormone, Vitamin B-12, prolactin, and progesterone) to the bulk serum in varying concentrations.

The serum is sterile filtered and dispensed in six mL aliquots into individual glass serum vials. The vials are then capped with a rubber stopper and metal seal and stored frozen.

Approximately 430 laboratories participate in the endocrinology proficiency testing program that is administered three times per year. Five serum vials are sent to each laboratory enrolled in the NYS program for evaluation.

Hematology Proficiency Testing

The proficiency test package consists of five stabilized whole blood products, five lyophilized plasma samples for coagulation studies, five lyophilized plasma samples for fibrinogen testing, and photographic transparencies for cell identification.

The stabilized whole blood products (HP-5 materials) are purchased from a licensed manufacturer and are tested and found nonreactive for HBsAg and anti-HIV. The 1.5 mL samples are shipped by the manufacturer in 5 mL vacutainers.

The lyophilized plasma samples for coagulation studies and fibrinogen are purchased from a licensed manufacturer and are tested and found nonreactive for HBsAg, anti-HIV and anti-HCV. The one mL samples are packaged by the manufacturer in 5 mL Wheaton vials with a flanged rubber stopper and plastic screw-top caps.

Approximately 500 laboratories participate in the Hematology proficiency testing program that is administered three times per year.

Oncology Proficiency Test

The proficiency samples are prepared in a non-human, protein-based matrix of 6% bovine serum albumin that is purchased from a licensed manufacturer.

The Wadsworth Center staff adds the analytes alpha-fetoprotein (AFP), CA125, CA15-3, CA19-9, CA27.29, Carcinoembryonic antigen (CEA) and prostate specific antigen (PSA) to the matrix in varying, very small concentrations ($\mu\text{g/L}$). All analytes are either from cell culture or human sources and have been screened by the manufacturer for HIV and hepatitis virus.

The samples are sterile filtered and aseptically dispensed in five mL aliquots into individual glass serum vials using a GMP process. The vials are then capped leakproof with a rubber stopper and metal seal and stored refrigerated.

Approximately 320 laboratories participate in the Oncology proficiency testing program that is administered three times per year. Five serum vials are sent to each laboratory enrolled in the NYS program for evaluation.

Parasitology Proficiency Test

The proficiency samples are purchased from a licensed manufacturer. The test kit consists of three fecal specimens suspended in 1.5 mL of 10% formalin, one unstained methanol fixed blood smear for malaria and one unstained PVA fixed fecal smear.

Approximately 180 laboratories participate in the parasitology proficiency testing program that is administered three times per year. Five samples as defined above are sent to each laboratory enrolled in the NYS program for evaluation.

Therapeutic Substance Monitoring (TSM) Proficiency Test

The proficiency samples are prepared from bulk serum that is purchased from a licensed manufacturer. The bulk serum has been tested and found negative for HBsAg, anti-HIV-1, anti-HIV-2, HIV-1 antigen and anti-HCV and the results of the testing are provided by the manufacturer.

The Wadsworth Center staff adds the drugs (ethanol, acetaminophen, carbamazepine, digoxin, ethosuximide, gentamicin, lithium, N-acetyl procainamide, phenobarbital, phenytoin, primidone, procainamide, quinidine, salicylate, theophylline, tobramycin, valproic acid, vancomycin) to the bulk serum in varying concentrations.

The serum is sterile filtered and dispensed in five mL aliquots into individual glass serum vials. The vials are then capped with a gray butyl stopper and metal seal and stored frozen.

Approximately 350 laboratories participate in the TSM proficiency testing program that is administered three times per year. Five serum vials are sent to each laboratory enrolled in the NYS program for evaluation.

Clinical and Forensic Toxicology Proficiency Test

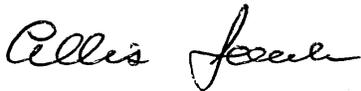
The proficiency samples are prepared from urine that is collected from healthy volunteer donors. The Wadsworth Center staff adds the drugs (Amphetamines, barbiturates, benzodiazepines, benzoylecgonine, ethanol, fentanyl, methadone, opiates, phencyclidine, propoxyphene, THC-cannabinoids, tricyclic antidepressants) to the urine in varying concentrations.

The urine is filtered and dispensed in 50 mL aliquots into plastic containers and/or into 10 mL aliquots in Wheaton glass serum bottles, gray butyl stopper, aluminum seal, crimped and frozen.

Approximately 250 laboratories participate in the Clinical and Forensic Toxicology proficiency testing program that is administered three times per year. Four to eight vials are sent to each laboratory enrolled in the NYS program for evaluation.

We look forward to hearing from you soon regarding our interpretation of the new shipping regulations. If you have any questions or need further information, you may contact Kathi Wagner at (518) 485-5399.

Sincerely,



Ellis Jacobs, Ph.D., DABCC
Director, Clinical Laboratory Evaluation Program