



**Virology Serology Laboratory
Specimen Submission Guidelines**

**Kansas Department of Health and Environmental Laboratories
6810 SE Dwight Street
Topeka, Kansas 66620
Phone: (785) 296-1620
Fax (785) 559-5208**

General Information

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Laboratory Director: N. Myron Gunsalus, Jr.

Health Section Chief: Caryn Masters, MS

Virology/Serology Laboratory Manager: Brian Hart

Address: Kansas Department of Health and Environmental Laboratories
6810 SE Dwight Street
Topeka, Kansas 66620

Phone Number: (785) 296-1620

Fax Number: (785) 559-5208

Hours of Operation:

Open Monday through Friday 8:00am to 5:00pm.

KHEL does not perform testing and observes the following holidays:

New Year's Day (*January 1**)
Martin Luther King, Jr, Day (3rd Monday of January)
Memorial Day (Last Monday of May)
Independence Day (*July 4**)
Labor Day (1st Monday of September)
Veteran's Day (*November 11**)
Thanksgiving (4th Thursday and Friday of November)
Christmas Day (*December 25**)

**When a holiday falls on Saturday, it is observed on the preceding Friday. When a holiday falls on Sunday, it is observed on the following Monday.*

Website: <http://www.kdheks.gov/labs/index.html>

The purpose of this manual is to provide a ready reference to our clients and to assist them in obtaining laboratory services as efficiently as possible.

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The policy of the Kansas Department of Health and Environmental Laboratories (KHEL) is to provide clinical specimen testing support to county and state agencies. This information is also used as part of the Kansas Department of Health and Environment (KDHE) Epidemiology and

Public Health Informatics infectious disease surveillance program. The KDHE Infectious Disease Epidemiology and Response program conducts infectious disease surveillance and outbreak investigations and provides subject matter expertise to local health departments, physicians, veterinarians, and the general public.

KDHE reporting requirements can be found at http://www.kdheks.gov/epi/disease_reporting.html. This report identifies diseases which must be reported to the state and which specimens must be submitted to the laboratory. Please follow packaging and shipping guidelines found in this manual or on our website at http://www.kdheks.gov/labs/packaging_and_shipping.html to submit specimens to KHEL.

Further information regarding specimen collection materials, mailing containers and *Requisition for Laboratory Specimen Kits and Supplies* form is located in this manual. Supplies ordered from KHEL are to be used ONLY to submit specimens to KHEL. All requisitions for specimen kits and supplies for specimen submission can be requested by mailing or faxing the KHEL Customer Service unit in Topeka:

Kansas Department of Health and Environmental Laboratories
ATTN: Customer Service
6810 SE Dwight Street
Topeka, Kansas 66620
Fax: (785) 559-5205

http://www.kdheks.gov/labs/cust_serv/download/specimen_kit_request_form.pdf

Please request specimen collection materials and mailers before they are required as the expected turnaround time per order is **FIVE** business days. Most materials do have a limited shelf life; therefore, only order what will be used before the expiration date. Please do not use expired kits or any kits in which the media has changed characteristics. Dispose of the media properly and order replacement supplies.

The Clinical Laboratory Improvement Act (CLIA) regulations require a unique patient identifier on both the specimen container and the KDHE Universal Laboratory Specimen Submission Form (Health). For example, each specimen must be properly labeled with at least the barcode label from the KDHE Universal Laboratory Specimen Submission Form (Health).

KHEL specimen submission guidelines are referenced from the guiding principles set forth by the Clinical and Laboratory Standards Institute (CLSI) and the Centers for Disease Control and Prevention (CDC).

Specimen Rejection Guidelines

KHEL currently has the following policy for rejection of laboratory specimens and/or requested examinations. KHEL will NOT examine clinical/reference specimens if the following circumstances exist:

- The patient identifier on the specimen did not match the identifier on the submission form, or there was no identification on the specimen.
- The quantity of specimen was not sufficient for examination.
- The quality of specimen was not sufficient for examination.
- The quantity of specimen did not meet the specimen collection guidelines.
- The transit time for the specimen exceeded the maximum allowable time frame from the time of collection to receipt by the laboratory.
- The specimen was broken or leaked in transit.
- Specimen was submitted in an improper or expired container, transport media, or preservative.
- Blood/serum specimens submitted for analysis were grossly hemolyzed or contaminated.
- Test request deemed unnecessary by the Bureau of Epidemiology and Public Health Informatics program and/or the Sexually Transmitted Infection (STI)/HIV program.

Exceptions to this policy will be considered due to extenuating circumstances; however, final approval to make an exception can only be made by the Laboratory Director, Health Section Chief, or Virology/Serology Laboratory Manager.

Category B Shipping Guidelines

FedEx Overnight and 2Day and UPS Next Day Air and Ground services are encouraged as the delivery times are guaranteed by the carriers. The use of a commercial carrier service is also encouraged if specimens are delivered to KHEL within the window of the collection date and time requirements. The use of USPS is discouraged for all clinical specimen testing as the delivery times are not guaranteed by the carrier.

*Please note specific collection requirements for each clinical specimen test type, as specimens received outside of those conditions will be rejected for testing. Specimen collection is encouraged Monday through Thursday with delivery to KHEL Monday through Friday by 10:00 am. Specimen collection is not encouraged on Fridays or the day before a holiday (See page 2 for list of observed state holidays). All clinical specimens received by 4:00 pm Monday through Friday will be processed the same day. Specimens received after 4:00 pm Monday through Friday will be processed the following business day.

All infectious material must be classified as either Category A (UN2814, Infectious substances, affecting humans, 6.2) or Category B (UN3373) and must be transported to KHEL according to appropriate IATA (International Air Transportation Association www.iata.org), USPS (United States Postal Service www.usps.com) and DOT (U.S. Department of Transportation www.transportation.gov) shipping regulations. All infectious material must be triple-packaged to protect against breakage and/or leakage during transportation. All specimens and must be in leak proof containers with absorbent material, and properly fastened screw caps.

Package Marking and Label Requirements

Note: All routine screening specimens for the Virology Serology Laboratory utilize Category B shipping requirements.

- Category B
 - [Checklist for Category B, Biological Substances](#)
 - Proper shipping name and UN3373 label
 - Name and telephone number of responsible person
 - May be placed on separate document such as air waybill
 - Orientation arrows (as applicable)

No shipping papers required unless not under exception. Substances which are unlikely to cause disease in humans or animals or do not contain infectious substances are not subject to the Regulations unless they meet criteria for inclusion in another class.

Submit all specimens to:

Kansas Department of Health and Environmental Laboratories
6810 SE Dwight Street
Topeka, Kansas 66620
(785) 296-1620

Virology Serology Laboratory Specimen Specific Test Requirements

Chlamydia/Gonorrhea (CTGC)

- Purpose: To provide public health testing services to help identify and stop the spread of sexually transmitted diseases.
- Acceptable Specimens
 - Endocervical swab
 - Pharyngeal (Throat) swab
 - Rectal swab
 - Urethral swab
 - Urine
 - Vaginal swab
- Collection Instructions
 - These specimens must be submitted in Hologic Aptima collection devices. These collection devices are not provided by KHEL, and must be purchased directly from Hologic.
 - Aptima Male and Female Urine Specimen Collection Kit :
https://www.hologic.com/sites/default/files/package-insert/502260-IFU-PI_002_01.pdf
 - Aptima Multitest Swab Specimen Collection Kit for vaginal swab specimens: https://www.hologic.com/sites/default/files/2018-01/AW-15641-REG_002_01_0.pdf
 - Aptima Unisex Swab Specimen Collection Kit for Endocervical, rectal, throat and Male Urethral Swab Specimens:
https://www.hologic.com/sites/default/files/package-insert/502258-IFU-PI_002_01.pdf
 - The following link provides detailed information about collection instructions for this test:
http://www.kdheks.gov/sti_hiv/download/Guidlines_for_Gen_Probe_Sample_Submission.pdf
- Rejection Criteria
 - Collection devices submitted must not be expired.
 - Correct specimen collection device must be used for source submitted.
 - Swabs submitted for analysis must not exceed maximum swab length.
 - Urine tubes submitted for analysis must be between the fill lines.
- Transport and Storage
 - After collection, store specimen and transport to KHEL in collection devices at 2 – 30°C. Specimens should be shipped as soon as possible after collection.
 - Urine specimens must be received within 30 days of collection.
 - Swab specimens must be received within 60 days of collection.
 - http://www.kdheks.gov/labs/downloads/Chlamydia_Packaging_Handout.pdf
- Turnaround Time: 2 – 4 Business days from receipt by the Virology Serology Laboratory.

Blood/Serum tests (HIV, Syphilis, Hepatitis B & C and Rubella)

- Purpose: To provide public health testing services to help identify and stop the spread of sexually transmitted diseases. Additionally, this testing is used to provide public health testing for prenatal clients at local health departments and other community based organizations.
- Acceptable Specimens
 - Serum
- Collection Instructions
 - Collect a blood specimen in serum separator tube (SST). Follow manufacturer's instructions for serum processing or see below steps.
 - Gently invert 5 times.
 - Allow blood to clot for at least 30 minutes. Centrifugation must be performed within 2 hours of collection.
 - Centrifuge for 10 minutes at 1000-1300 RCF (g) in a swinging bucket centrifuge or 15 minutes in a fixed-angle centrifuge.
 - Label provided pour-off tube(s) with two patient identifiers and KDHE Universal Laboratory Specimen Submission form barcode label.
 - Remove cap and pour serum into provided pour-off tube.
 - Required serum volume is 2mL per requested test.
 - HIV specimens should be submitted in separate pour-off tube from multiple test requests.
 - Other serum tests for a patient may be pooled into a single pour-off tube, as long as minimum volume requirements are met.
 - HIV and Syphilis specimens must be poured off.
 - Hepatitis B & C, and Rubella specimens may be shipped in SST.
 - Serum specimens must be received at KDHE Laboratory within the following guidelines:
 - 48 hours for Rubella
 - 5 days for Syphilis
 - 7 days for HIV
 - 7 days for Hepatitis B & C (may be sent at ambient temperatures, if these are the only tests requested)
 - Serum specimens that will be in transit longer than these times must be frozen at -20°C or below. Note: specimens for syphilis may only be frozen up to 14 days prior to testing.
 - If frozen, the freeze date/time must be written in the "Special Notes" section of the form. Failure to do so will result in a rejection of the specimen.
 - The total time from collection to frozen plus transit time receipt at KHEL cannot exceed the listed requirements for each test requested.
- Rejection Criteria
 - Specimen not poured off and shipped on ice packs, when indicated
 - Received after more than allowable number of days post collection
- Transport and Storage

- All serum and CTGC specimens can be packaged in same box for shipping, if desired. Note and follow most restrictive shipping conditions for tests requested.
- Refrigerate serum and ship on ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
- http://www.kdheks.gov/labs/downloads/Serum_Cold_Shipper_Guide.pdf
- Turnaround Time
 - HIV and Syphilis: 2 – 4 business days from receipt by the Virology Serology Laboratory.
 - Hepatitis B, C and Rubella: 3 – 7 business days from receipt by the Virology Serology Laboratory.

Herpes PCR

- Purpose: To provide public health testing services to help identify, and stop the spread of sexually transmitted diseases.
- Acceptable Specimens
 - Swab from an active lesion
- Collection Instructions
 - Collect a specimen from an active genital, mouth or skin lesion, with a sterile Dacron or polyester-tipped swab (non-wooden shaft).
 - Place swab in Viral Transport Medium (VTM) or Universal Transport M4 Medium (UTM)
- Rejection Criteria
 - Received more than 7 days post collection
 - Specimen not shipped on ice packs
 - Specimen not submitted in correct media or swab type
- Transport and Storage
 - Refrigerate and ship on ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
 - Ensure shipper has a refrigerate label or “REFRIGERATE” written on the box.
 - Must be received at KHEL within 7 days of collection.
 - http://www.kdheks.gov/labs/downloads/Virus_pictorial_guide.pdf
- Turnaround Time
 - 3 – 5 Business days from receipt by the Virology Serology Laboratory

Influenza PCR

- Purpose: Testing performed for Influenza-Like Illness Network (ILINet) sites for public health surveillance, hospitalized patients, or for outbreak testing with Bureau of Epidemiology and Public Health Informatics approval.
- Acceptable Specimens
 - Respiratory specimens approved for testing:
 - Nasopharyngeal swab (preferred)
 - Nasal swab, aspirate, or wash
 - Throat swab
 - Bronchial wash

- Collection Instructions
 - Collect with a sterile Dacron or polyester-tipped swab (non-wooden shaft).
 - Place swab or respiratory specimen in Viral Transport Medium (VTM) or other M4 Universal Transport Medium (UTM)
- Rejection Criteria
 - Specimen not shipped on ice packs
 - Received more than 3 days post collection
 - Specimen not submitted in correct media or swab type
- Transport and Storage
 - Refrigerate and ship on ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
 - Ensure shipper has a refrigerate label or “REFRIGERATE” written on the box.
 - Must be received at KHEL within 3 days of collection.
 - Specimens may alternatively be frozen at -70°C or below and shipped on dry ice to remain frozen, if transit needs to be delayed. If frozen, the freeze date/time must be written in the “Special Notes” section of the form. Failure to do so will result in a rejection of the specimen.
 - http://www.kdheks.gov/labs/downloads/Virus_pictorial_guide.pdf
- Turnaround Time
 - 3 – 5 Business days from receipt by the Virology Serology Laboratory.

Specimens requiring KDHE Epidemiology Approval

(Contact KDHE Epidemiology Hotline 1-877-427-7317 for consultation and approval)

Measles PCR

- Purpose: Testing performed for suspected disease outbreak testing with Bureau of Epidemiology and Public Health Informatics (BEPHI) approval.
- Acceptable Specimens
 - Respiratory specimens approved for testing:
 - Nasopharyngeal swab (preferred)
 - Throat swab
 - Urine
- Collection Instructions
 - Collect respiratory specimen with a sterile Dacron or polyester-tipped swab (non-wooden shaft).
 - Place swab or respiratory specimen in Viral Transport Medium (VTM) or other M4 Universal Transport Medium (UTM).
 - Urine
 - Centrifuge 10 – 50mL of urine (500 x g /about 1500 RPM) for 10 minutes, preferably at 4°C.
 - Resuspend the sediment in 2-3 mL of sterile transport medium
- Rejection Criteria
 - Specimen received without prior BEPHI approval
 - Specimen not shipped on ice packs
 - Received more than 3 days post collection
 - Specimen not submitted in correct media or swab type
- Transport and Storage
 - Refrigerate and ship on ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
 - Ensure shipper has a refrigerate label or “REFRIGERATE” written on the box.
 - Must be received at KHEL within 3 days of collection.
 - Specimens may alternatively be frozen at -70°C or below and shipped on dry ice to remain frozen, if transit needs to be delayed. If frozen, the freeze date/time must be written in the “Special Notes” section of the form. Failure to do so will result in a rejection of the specimen.
 - http://www.kdheks.gov/labs/downloads/Virus_pictorial_guide.pdf
- Turnaround Time
 - 1 – 2 Business days from receipt by the Virology Serology Laboratory

Mumps PCR

- Purpose: Testing performed for suspected disease outbreak testing with Bureau of Epidemiology and Public Health Informatics (BEPHI) approval.

- Acceptable Specimens
 - Buccal swab
- Collection Instructions
 - Collect a buccal specimen with a sterile Dacron or polyester-tipped swab (non-wooden shaft). Collect specimen as soon as possible, within 3 days of parotitis onset/observation.
 - Place swab specimen in Viral Transport Medium (VTM) or other M4 Universal Transport Medium (UTM)
- Rejection Criteria
 - Specimen received without prior BEPHI approval
 - Specimen not shipped on ice packs
 - Received more than 3 days post collection
 - Specimen not submitted in correct media or swab type
- Transport and Storage
 - Refrigerate and ship on ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
 - Ensure shipper has a refrigerate label or “REFRIGERATE” written on the box.
 - Must be received at KHEL within 3 days of collection.
 - Specimens may alternatively be frozen at -70°C or below and shipped on dry ice to remain frozen, if transit will be delayed. If frozen, the freeze date/time must be written in the “Special Notes” section of the form. Failure to do so will result in a rejection of the specimen.
 - http://www.kdheks.gov/labs/downloads/Virus_pictorial_guide.pdf
- Turnaround Time
 - 1 – 2 Business days from receipt by the Virology Serology Laboratory.

Respiratory Panel PCR

- Purpose: Testing performed for Influenza-Like Illness Network (ILINet) sites for public health surveillance, hospitalized patients, or for outbreak testing with Bureau of Epidemiology and Public Health Informatics approval.
- Acceptable Specimens
 - Nasopharyngeal swab
- Collection Instructions
 - Collect a nasopharyngeal specimen with sterile Dacron or polyester-tipped swab (non-wooden shaft).
 - Place swab specimen in Viral Transport Medium (VTM) or other M4 Universal Transport Medium (UTM).
- Rejection Criteria
 - Specimen received without prior BEPHI approval
 - Specimen not shipped on ice packs
 - Received more than 3 days post collection
 - Specimen not submitted in correct media or swab type
- Transport and Storage

- Refrigerate and ship on ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
- Ensure shipper has a refrigerate label or “REFRIGERATE” written on the box.
- Must be received at KHEL within 3 days of collection.
 - Specimens may alternatively be frozen at -15°C or below and shipped on dry ice to remain frozen, if transit will be delayed. If frozen, the freeze date/time must be written in the “Special Notes” section of the form. Failure to do so will result in a rejection of the specimen.
- http://www.kdheks.gov/labs/downloads/Virus_pictorial_guide.pdf
- Turnaround Time
 - 1 – 3 Business days from receipt by the Virology Serology Laboratory.

Norovirus PCR

- Purpose: Testing performed for suspected disease outbreak investigations with Bureau of Epidemiology and Public Health Informatics (BEPHI) approval.
- Acceptable Specimens
 - Stool
- Collection Instructions
 - Collect a quarter sized amount of stool and transfer into a Cary-Blair transport medium vial within two hours of collection.
- Rejection Criteria
 - Specimen received without prior BEPHI approval
 - Received more than 7 days post collection
 - Specimen not submitted in correct media
- Transport and Storage
 - Must be received by KHEL within 7 days of collection. Note: If gastrointestinal panel testing required, specimen must be received within 4 days of collection.
 - Ship cold (ideal) or at room temperature in an Enteric with Cary Blair mailer with a Biological Substance, Category B – Enteric/Misc Bacterial shipping label.
 - http://www.kdheks.gov/labs/downloads/clinical_specimen_feces_bacterial_culture_handout.pdf
- Turnaround Time
 - 1 – 3 Business days from receipt by the Virology Serology Laboratory.

West Nile Virus

- Purpose: Testing performed for public health surveillance with Bureau of Epidemiology and Public Health Informatics (BEPHI) approval who present with neuroinvasive disease including encephalitis or meningitis.
- Acceptable Specimens
 - Human serum
- Collection Instructions
 - Collect a blood specimen in serum separator tube (SST). Follow manufacturer’s instructions for serum processing or see below steps.
 - Gently invert 5 times.

- Allow blood to clot for at least 30 minutes. Centrifugation must be performed within 2 hours of collection.
- Centrifuge for 10 minutes at 1000 – 1300 RCF (g) in a swinging bucket centrifuge, or 15 minutes in a fixed-angle centrifuge.
- Remove cap and pour serum into provided or standard serum pour-off tube. Required serum volume is 2 to 5mL.
- Rejection Criteria
 - Specimen received without prior BEPHI approval
 - Specimens not received with the following criteria: 2 – 8°C within 48 hours of collection, or frozen at -70°C or below and shipped on dry ice.
- Transport and Storage
 - Refrigerate and ship on frozen ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
 - Alternatively, ship frozen serum in Biological Substance, Category B insulated mailer with dry ice.
 - Ensure shipper has a refrigerate label or “REFRIGERATE” written on the box.
 - Specimens should be received at KDHE Laboratory within 2 days of collection, if not sent frozen.
- Turnaround Time
 - 3 – 7 Business days from receipt by the Virology Serology Laboratory

Zika Virus

- Purpose: Testing performed for public health surveillance with Bureau of Epidemiology and Public Health Informatics (BEPHI) approval.
- Acceptable Specimens
 - Serum
 - Urine
- Collection Instructions
 - Detailed collection and shipping instructions are available at <http://www.kdheks.gov/labs/downloads/ZikaShipping.pdf>
 - Collect a blood specimen in serum separator tube (SST). Follow manufacturer’s instructions for serum processing or see below steps.
 - Gently invert 5 times.
 - Allow blood to clot for at least 30 minutes. Centrifugation must be performed within 2 hours of collection.
 - Centrifuge for 10 minutes at 1000 – 1300 RCF (g) in a swinging bucket centrifuge, or 15 minutes in a fixed-angle centrifuge.
 - Remove cap and pour serum into provided or standard serum pour-off tube. Required serum volume is 2 to 5mL.
 - Urine specimens must be submitted with a paired serum specimen.
 - Specimens should be sent in provided or standard urine collection tube. Urine cups often leak during transit and are thus discouraged. Required volume is 2 to 5mL.
- Rejection Criteria

- Specimen received without prior BEPHI approval
 - Received more than 3 days post collection
- Transport and Storage
 - Refrigerate and ship on ice packs in a Biological Substance, Category B insulated mailer to be received at 2 – 8°C.
 - Ensure shipper has a refrigerate label or “REFRIGERATE” written on the box.
 - Specimens should be received at KDHE Laboratory within 3 days of collection.
- Turnaround Time
 - 3 – 7 Business days from receipt by the Virology Serology Laboratory