

Wichita Falls-Wichita County Public Health District Laboratory

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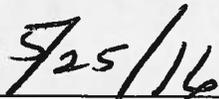
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Laboratory Guide

Reviewed and approved:


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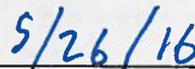

Date

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INTRODUCTION:

The Wichita Falls-Wichita County Public Health District Laboratory is a fully staffed, fully accredited Clinical Laboratory. It possesses Clinical Laboratory Improvement Amendments (CLIA) certificate #45D0672374. The laboratory is additionally certified by the Texas Department of State Health Services (DSHS), the Environmental Protection Agency (EPA), and the Texas Commission on Environmental Quality (TCEQ) to provide water testing in support of Public Law 93-523, the Federal Safe Drinking Water Act, and for the Federal Information Coliform Rule (ICR) testing. It participates in several quality control and quality assurance blind testing and proficiency monitoring surveys and meets or exceeds all local, state, and federal requirements for clinical laboratories.

PURPOSE: The purpose of this guide is to familiarize the various agencies and personnel who utilize the Wichita Falls-Wichita County Public Health District Laboratory of the services available, specimen collection procedures, turn-around-times, expected values, abnormal values, and other pertinent information of importance to those who use this laboratory.

GENERAL INFORMATION: The laboratory provides services for other Health District divisions as well as in-house clinic patients. Services are also provided for outside submitters in coordination with other county and state health agencies. Environmental monitoring for private parties is also accepted when appropriate.

The laboratory is staffed by a certified Consultant Laboratory Director and is managed by a certified and registered Medical Technologist/Clinical Scientist/Technical Supervisor. The remaining laboratory staff are all either registered Medical Technologists, Medical Laboratory Technicians, and/or are certified for any testing they perform.

The laboratory is located in the Public Health District building:

1700 Third Street
Wichita Falls, TX 76301-2113
(940) 761-7873 or (940) 761-7835

Appropriate submission forms for all types of samples are available in the laboratory. Internal submissions are available electronically on the Public Health Information Management System (PHIMS) for clinical and laboratory personnel. Please fill out each form in its entirety for each sample submitted. Improperly filling out a submission form is grounds for specimen rejection. The laboratory also offers complaint forms for the purpose of discrepancy investigation and quality improvement. A copy of this form is attached at the end of this Lab Guide, and is posted on the client boards at clinic locations. Any suggestions on how to improve the services provided by the laboratory are appreciated and encouraged.

HOURS OF OPERATION: The Health District Laboratory's normal hours of operation are Monday through Friday, 8:00 a.m. to 5:00 p.m. Samples will be accepted during normal work hours, **except** for drinking water samples for bacterial growth. These samples may be submitted only on Monday through Thursday, prior to 3:00 p.m. in order to allow sufficient time to set up the test samples before the end of the work day. Also, the water analysis requires a 24-hour incubation period and must be interpreted the following day.

HOLIDAYS: The laboratory is closed in observance of the following holidays: New Year's Day,

HOLIDAYS: The laboratory is closed in observance of the following holidays: New Year's Day, President's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving, day after Thanksgiving, Christmas Eve, and Christmas Day. Specimens for water analysis are not accepted the business day before an observed holiday. Exceptions to the hours of operation must be coordinated and approved by laboratory management and the Director of Public Health. Emergency testing is available with prior approval.

LABORATORY TESTS OFFERED:

GRAM STAIN

PRINCIPLE: In addition to culture, a direct smear of urethral discharge may be examined by Gram stain for the presence of gram-negative intracellular diplococci indicative of infection by *Neisseria gonorrhoea* in males. Presumptive diagnosis of gonorrhoea from vaginal discharge is not reliable because normal vaginal flora may resemble *Neisseria gonorrhoea*. Presence of a high number of leukocytes may also be indicative of vaginosis or urinary tract infection.

SPECIMEN: A direct smear of vaginal secretions or urethral discharge prepared on a clean glass slide. Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection. Slides are retained for one week after interpretation.

TURNAROUND TIME: <1 hour. Slides are stained and examined immediately upon receipt in the laboratory.

EXPECTED RESULTS:

Female: <10 WBCs, occasional epithelial cells, presence of bacteria consistent with normal vaginal flora, no other cellular elements.

Male: < 2 WBCs, occasional epithelial cells, no other cellular elements.

ABNORMAL RESULTS:

Elevated WBC count, gram-negative intracellular or extracellular diplococci

WET MOUNT

PRINCIPLE: Direct microscopic examinations of a wet preparation of vaginal discharge can provide a rapid diagnosis of infection by *Trichomonas vaginalis*, presence of fungal elements, and bacterial vaginosis characterized by the presence of "clue cells."

SPECIMEN: Vaginal secretions collected on a sterile swab and transported to a tube containing 3 mL of sterile saline. Specimens must be delivered to the laboratory immediately following collection to protect the viability of *Trichomonas vaginalis* trophozoites. Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection.

TURNAROUND TIME: <1 hour. Wet mounts are examined immediately upon receipt in the laboratory.

EXPECTED RESULTS:

0-5 WBCs per high-power field (HPF), rare RBCs, occasional epithelial cells, moderate bacteria, no other cellular elements.

ABNORMAL RESULTS:

Elevated WBC count, *Trichomonas vaginalis*, fungal elements, clue cells.

DARKFIELD EXAMINATION:

PRINCIPLE: Treponemes can be detected in material taken from skin lesions by darkfield examination. It can be highly specific for *Treponema pallidum* when performed on genital lesions if syphilis infection is suspected.

SPECIMEN: Material for microscopic examination is collected from suspicious lesions by first cleansing the area around the lesion. The surface of the ulcer is abraded until some blood is exposed. After blotting the lesion until there is no further bleeding, the area is squeezed until serous fluid is expressed. Using a sterile pipette, transfer the fluid from the lesion to a glass slide with Vaseline. Gently cover the specimen with a glass cover slip and immediately deliver the sample to the laboratory. Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection.

NOTE: Please notify the laboratory before collecting the sample so all equipment can be ready when the specimen is delivered.

TURNAROUND TIME: 1 hour.

EXPECTED RESULTS:

No treponemal organisms found.

ABNORMAL RESULTS:

Treponemal organism found.

Failure to find the organism does not exclude a diagnosis of syphilis. Absence of spirochetes may mean that an insufficient number of organisms was present, the patient received antitreponemal drugs, the lesion was approaching natural resolution, or the lesion was not syphilitic.

When patients are strongly suspected of having primary syphilis, serological blood tests should be repeated in one week, one month, and three months. If nonreactive serological results are obtained for longer than three months in untreated patients, then syphilis may be excluded.

RAPID PLASMA REAGIN (RPR):

PRINCIPLE: RPR is a qualitative and semiquantitative nontreponemal flocculation test for the detection of reagin antibodies as a screening test for syphilis.

SPECIMEN: Serum (blood collected in a red or gold top). A minimum of 2 mL is needed for this test, but at least 4 mL is recommended to allow for titer and confirmatory testing. Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection.

TURNAROUND TIME: Same day testing. However, specimens received late in the business day may be tested on the following business day. Serum samples are retained in the laboratory for 1 week to allow for retesting.

STAT testing is available at the request of the ordering provider. Please note that turnaround times will be affected by current laboratory staffing levels.

NOTE: STAT testing puts all other laboratory operations on hold until the test results are reported to the ordering provider. STAT test results are immediately reported to clinical personnel. When requesting that a test be run STAT, it is the ordering provider's responsibility to ensure that a qualified staff member is available to receive the test results once they are completed.

EXPECTED RESULTS:

Nonreactive

ABNORMAL RESULTS:

Reactive

A Serodia®-TP·PA confirmatory test will be ordered by laboratory staff for all reactive RPRs if the patient has not had a reactive TP·PA in the past.

False-reactive results may occur in samples from individuals with a history of drug abuse, or with diseases such as lupus erythematosus, malaria, vaccinia, mononucleosis, leprosy, viral pneumonia, pinta, yaws, bejel, other treponemal diseases, or after smallpox vaccinations.

SERODIA®-TREPONEMA PALLIDUM PARTICLE AGGLUTINATION ASSAY (TP·PA):

PRINCIPLE: The Serodia®-TP·PA uses an antigen for the detection of *Treponema pallidum* antibodies to aid in the diagnosis of syphilis. This is a confirmatory test and should only be ordered after a reactive nontreponemal assay (RPR) is observed.

Patients who display a reactive TP·PA result will be reactive for life. There is no need to retest a patient for subsequent syphilis infections.

SPECIMEN: Serum (blood collected in a red or gold top). Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection.

TURNAROUND TIME: 24 hours. Specimens received late in the business day before a weekend or holiday will be tested on the following business day. Serum samples are retained in the laboratory for 1 week to allow for retesting.

EXPECTED RESULTS:

Nonreactive

ABNORMAL RESULTS:

Reactive

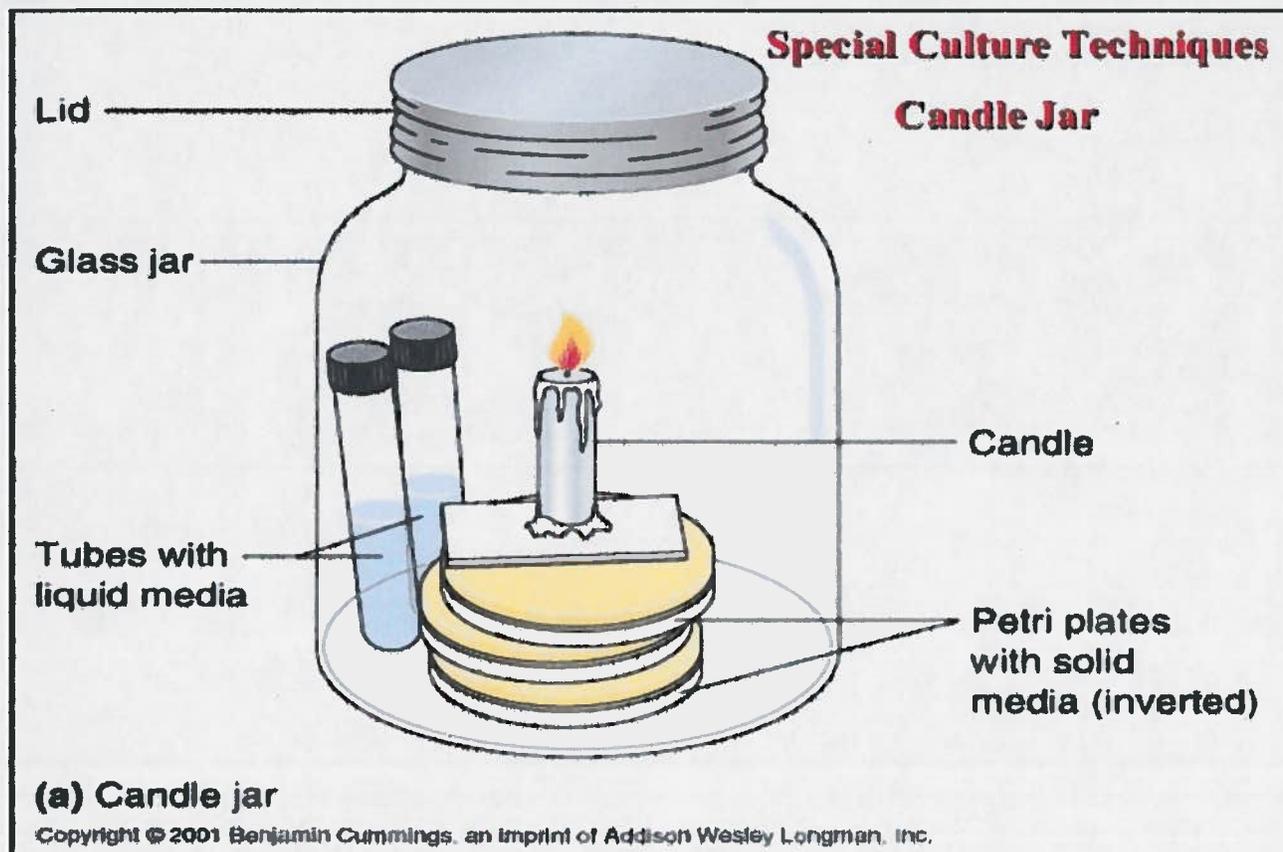
Patients with yaws, pinta, HIV, leprosy, toxoplasmosis, *Helicobacter pylori* infection, arthritis, or drug addiction may display false-reactive or inconclusive results.

NEISSERIA GONORRHEA CULTURE:

PRINCIPLE: *Neisseria gonorrhoea* is a leading cause of sexually transmitted infections, and infections caused by this organism usually are localized to the mucosal surfaces in the area of initial exposure (e.g., cervix, conjunctiva, pharyngeal surface, anorectal area, or urethra). Localized infections can be acute with a pronounced purulent response, or they may be asymptomatic. Not all infections remain localized, and dissemination from the initial infection site can lead to severe disseminated disease. Culture is the gold standard for detection and is considered diagnostic as *Neisseria gonorrhoea* is not part of normal human flora.

Although resistance to penicillin by production of beta-lactamase has become widespread among *N. gonorrhoea*, resistance to ceftriaxone, which is not notably affected by the enzyme, has not been described. Therefore, routine sensitivity testing of isolates to guide antimicrobial therapy does not appear to be necessary. On the other hand, quinolones also are widely used to treat gonorrhea, but resistance to these agents is emerging.

SPECIMEN: All specimens must be inoculated to a Modified Thayer Martin (MTM) agar plate. Samples collected on-site must be transported at room temperature immediately to the laboratory. Samples collected off-site must be placed in a candle jar. Light the candle within 15 minutes of the first sample collection, and the candle must be re-lit after each opening. Transport the candle jar to the laboratory as soon as possible on the day of collection. Maintain the inoculated agar plates at room temperature for transport. Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection.



***NEISSERIA GONORRHEA* CULTURE (continued):**

TURNAROUND TIME: Cultures are read at 24-hour intervals, and a negative result will be finalized after 48 hours of incubation. Positive cultures will be finalized after identification of *Neisseria gonorrhoea*.

EXPECTED RESULTS:

Negative for *Neisseria gonorrhoea*

ABNORMAL RESULTS:

Any positive result

Neisseria gonorrhoea will be presumptively identified by Gram stain and the production of oxidase. A positive result from a non-genital site or from a minor under 18 years of age will be confirmed through biochemical testing. Please note, biochemical confirmation takes an additional 24 hours to complete.

URINE PREGNANCY TEST (β -HCG):

PRINCIPLE: Qualitative detection of human chorionic gonadotropin (hCG) can aid in the detection of pregnancy as early as 7 to 10 days after conception.

SPECIMEN: Urine collected in a clean container. First morning urine samples are preferred because they generally contain the highest concentration of hCG; however, urine samples collected at any time of day are acceptable. Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection.

TURNAROUND TIME: <1 hour. Urine pregnancy tests are performed immediately upon receipt in the laboratory. Urine samples are retained in the laboratory for 24 hours to allow for retesting.

EXPECTED RESULTS:

Negative for males and non-pregnant females

Positive for pregnant females

A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. A confirmed pregnancy diagnosis should only be made after all clinical and laboratory findings have been evaluated.

SHIP-OUTS:

Common tests sent to reference laboratories are included in the table below. Specialty tests not listed here may be available. Please contact the laboratory at (940) 761-7862 or (940) 761-7835 for authorization and guidance when requesting a test that is not routinely ordered. Turnaround times for ship-out tests vary depending on the test ordered and the performing laboratory. Specimens must be labeled with the patient's name, unique identifier (i.e. date of birth, client #), and date of collection.

Test	Specimen	Performing Laboratory
CBC or Hgb/Hct	Whole blood collected in an EDTA (purple top) tube	Center for Disease Detection San Antonio, Texas
Gen-Probe for <i>Chlamydia/gonorrhea</i>	Urethral or Cervical Swab	Tarrant County Public Health North Texas Regional Laboratory Ft. Worth, Texas
Glucose (serum)	Serum (gold top)	Center for Disease Detection San Antonio, Texas
Hemoglobin A1C	Whole blood collected in an EDTA (purple top) tube	Center for Disease Detection San Antonio, Texas
Hepatitis Panel	Serum (gold top)	Center for Disease Detection San Antonio, Texas
Hepatitis B Surface Antibody	Serum (gold top)	Center for Disease Detection San Antonio, Texas
Hepatitis C Antibody	Serum (gold top)	Center for Disease Detection San Antonio, Texas
HIV	Serum (gold top)	Texas Department of State Health Services Austin, Texas
HSV IgG 1/2	Serum (gold top)	Center for Disease Detection San Antonio, Texas
Lead	Whole blood collected in a low-lead (tan top) tube	Center for Disease Detection San Antonio, Texas
Measles Antibody	Serum (gold top)	Center for Disease Detection San Antonio, Texas
Mumps Antibody	Serum (gold top)	Center for Disease Detection San Antonio, Texas
Rabies Antibodies	Serum (red top)	Kansas State University Manhattan, Kansas
Rubella Antibodies	Serum (gold top)	Center for Disease Detection San Antonio, Texas
T-Spot TB Testing	Whole Blood collected in a heparin (green top) tube	Oxford Diagnostic Laboratory, Memphis, Tennessee

SHIP-OUTS (continued):

Note:

- HIV Combo Ag/Ab EIA Reference Range = Nonreactive
- The HIV testing is not, in and of itself, diagnostic for HIV infection and should be considered in conjunction with other laboratory test results, clinical presentation, and patient history. Only a physician should interpret the results.
- HIV screening performed by the 4th generation HIV Combo Ag/Ab EIA test for HIV detection do not distinguish between the presence of HIV antibodies or antigen in a sample. Additional supplemental tests will be automatically performed to verify the presence of HIV-1 p24 antigen or antibodies to HIV-1 or HIV-2.
- A person who has antibodies to HIV-1 is presumed to be infected with the virus, except a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV.

HIV Screening, multisport HIV-1/HIV-2 rapid test, and NAAT results:

HIV Combo Ag/Ab EIA	Multispot	Interpretation
Nonreactive	<i>(not performed)</i>	No serologic evidence of infection with HIV. Cannot exclude incubating or early HIV infection. Submit second sample in 3-4 weeks if clinically indicated.
Reactive	HIV-1	Presumptive evidence of HIV-1 infection: Based on EIA and MS HIV-1 Ab positive results, probable active HIV-1 infection. (NAAT is not indicated per CLSI guidelines). Refer to physician for care.
Reactive	HIV-2	Presumptive evidence of HIV-2 infection: Based on EIA and MS HIV-2 Ab positive results, probable active HIV-2 infection. (NAAT is not indicated per CLSI guidelines). Refer to physician for care.
Reactive	Nonreactive or Indeterminate / Undifferentiated / Invalid	Possible acute infection: Based on EIA and MS results, possible acute HIV infection (AHI). Test for NAAT to rule out AHI; if reactive, possible AHI. Refer to physician for care. If NAAT is nonreactive or not tested, submit second sample in 3-4 weeks to rule out HIV infection with HIV-1 or HIV-2.

WATER TESTING FOR TOTAL COLIFORMS:

SPECIMEN REQUIREMENTS:

1. A 100 mL water sample from the appropriate source, collected in an acceptable container (one obtained from the laboratory for this purpose and containing a sodium thiosulfate buffer). Home sterilized containers **are not acceptable** for analysis and testing will not be performed on samples collected in these types of containers.

NOTE: The volume of sample must be exactly on the 100 mL mark. Over-filled containers will be rejected due to the diluting effect of too much volume producing erroneous results. The sample should be kept on ice during transport to the laboratory. This will help to prevent overgrowth by the bacteria if present. **Do not freeze.**

2. This test can only be performed on individual water wells and those submitted by public municipalities. Private citizens who are on municipal systems must contact the municipality in charge of the water system to arrange for testing. Under **no** circumstances will tests of municipal systems be done for an individual.

3. Samples are accepted Monday through Thursday from 8:00 a.m. to 3:00 p.m. Samples **must** be in the laboratory prior to 3:00 p.m. and **must** be less than thirty (30) hours old for analysis. Late specimens and those exceeding the 30-hour limit will be rejected.

TURNAROUND TIME: 24 hours.

EXPECTED RESULTS:

Negative for Total Coliforms

ABNORMAL RESULTS:

Positive for Total and/or Fecal Coliforms

NOTE: Any positive result on a municipal water sample is immediately reported to the Texas Commission on Environmental Quality, Austin, Texas. All positive samples on municipal systems must be repeated within the time frame and in quantities as outlined by the Texas Water Commission. A chlorine residual test will be performed on each batch of samples delivered to the laboratory. Excess free or total chlorine is grounds for specimen rejection due to the bacteriological inhibitory characteristics of that chemical.

WATER TESTING FOR FECAL COLIFORMS (*Escherichia coli*):

SPECIMEN REQUIREMENTS:

1. A 200 mL water sample from the appropriate source, collected in an acceptable container (one obtained from the laboratory for this purpose and containing a sodium thiosulfate buffer). Home sterilized containers **are not acceptable** for analysis and testing will not be performed on samples collected in these types of containers. All fecal coliform samples **must** be accompanied by a laboratory request form, which includes a Chain-of-Custody.

NOTE: The volume of sample must be exactly on the 200 mL mark. Over-filled containers will be rejected due to the diluting effect of too much volume producing erroneous results. The sample should be kept on ice during transport to the laboratory. This will help to prevent overgrowth by the bacteria if present. **Do not freeze.**

2. This test can only be performed on individual water wells and those submitted by public municipalities. Private citizens who are on municipal systems must contact the municipality in charge of the water system to arrange for testing. Under **no** circumstances will tests of municipal systems be done for an individual.

3. Samples are accepted Monday through Thursday from 8:00 a.m. to 3:00 p.m. Samples **must** be in the laboratory prior to 3:00 p.m. and **must** be less than thirty (30) hours old for analysis. Late specimens and those exceeding the 30-hour limit will be rejected.

TURNAROUND TIME: 24 hours.

EXPECTED RESULTS:

Negative for Fecal Coliforms or colony count <10 col/100 mL

For Effluents, <600 col/100 mL

ABNORMAL RESULTS:

Fecal Coliforms Present with a colony count of >10 col/100 mL

For Effluents, ≥600 col/100 mL

NOTE: The level of possible pollution in a fecal coliform sample is a function of the water source, level of purity, and density of bacterial contamination. For help in this area, please contact the Texas Commission on Environmental Quality at: (512) 239-1108.

FROZEN DESSERTS/SOFT-SERVE ICE CREAM CULTURE:

SPECIMEN REQUIREMENTS:

1. 33 grams or 2 ounces of soft-serve mix of frozen sample should be collected by Environmental Health Sanitarians or Public Health Officers by aseptic technique and placed in a sterile whirl bag or other appropriate container and brought to the laboratory. The minimum amount required for analysis is 15 grams. Please refrigerate the samples during transport.

2. Upon arrival at the laboratory, the sample should be placed in the refrigerator until testing can be performed. Samples should reach the laboratory not later than noon for analysis.

3. Testing is performed on Monday, Tuesday, and Wednesday **only**. Environmental Health personnel should check with the laboratory **before** collecting samples for two reasons. First, the media for these tests must be prepared fresh and takes approximately 2 hours to prepare. Second, these tests are labor-intensive, and the laboratory needs to be notified to insure that staffing is available to perform this testing.

TURNAROUND TIME: 3 Business Days

ACCEPTABLE RANGES:

TYPE	SPC	COLIFORM (VRB)
Ices	<100,000 col/gm	<150 col/gm
Novelties	<200, 000 col/gm	<150 col/gm
Soft-serve Mix	<200, 000 col/gm	<150 col/gm
Soft-serve Frozen	<200, 000 col/gm	<150 col/gm

Interpretation of report results will be made by the Environmental Health Division in consultation with laboratory staff.

UNACCEPTABLE RESULTS:

Any test that is above the acceptable range.

FOOD SAMPLES:**SPECIMEN REQUIREMENTS:**

1. Samples for the detection of food intoxication and/or food poisoning must be collected by Environmental Health Sanitarians or Public Health Officers. Samples must be collected aseptically in a sterile container using sterile equipment. Sample requirements are 100 mL for liquids and 33 g or 2 oz. for solids. A minimum of 15 g will be accepted.

2. Whenever a prepackaged food is suspect, the investigator will obtain an unopened package of the same lot #, stored under the same conditions as the representative sample. Both will be submitted for analysis and comparison.

TURNAROUND TIME: 2-6 Business Days.

EXPECTED RESULTS:

Negative or No Growth after 48 hours.

ABNORMAL RESULTS:

Any Enteric organism, *Staphylococcus aureus*, and certain *Streptococcus* spp. Other unique organisms may be implicated as well based on symptomatology, onset of illness/intoxication, and other factors. Consultation between the Laboratory and Environmental Health personnel may be necessary depending upon the organisms suspected or recovered.

NOTE: This facility does not perform anaerobic microbiological studies. Therefore, we are unable to test for *Clostridium* spp. or *Campylobacter* spp. Assistance from the Texas Department of State Health Services, Austin laboratory is required to test for these organisms.

CRITICAL VALUES:

The following table defines lab results that are considered "critical values" by the Wichita Falls-Wichita County Public Health District Laboratory. When one of these values is approved by laboratory staff, the ordering provider will be immediately contacted by the approving laboratory technician, and a note documenting the immediate delivery of results will be entered into the PHIMS report.

Test	Result
HIV Combo Ag/Ab EIA	Reactive HIV-1 and/or Reactive HIV-2
Rapid Plasma Reagin and Serodia®-TP·PA	A Reactive RPR coinciding with a Reactive Serodia®-TP·PA or history of Reactive Serodia®-TP·PA results
<i>Neisseria gonorrhoea</i> culture	Any growth of <i>Neisseria gonorrhoea</i>
Gen-Probe for <i>Chlamydia/gonorrhoea</i>	Positive for <i>Chlamydia</i> and/or <i>gonorrhoea</i>

SUMMARY OF REVISIONS:

DATE	SUMMARY OF REVISION	RESPONSIBLE PARTY