



**CITY AND COUNTY OF SAN FRANCISCO
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Test Order

***Chlamydia trachomatis* (NAAT Testing)**

Specimen Collection and Storage for *Chlamydia trachomatis* testing (using Alinity *m* multi-collect specimen collection kit)

Background: The Alinity *m* STI assay is an in vitro reverse transcription polymerase chain reaction (RT-PCR) assay for use with the automated Alinity *m* System for the direct, qualitative detection and differentiation of RNA from *Chlamydia trachomatis* (CT), DNA from *Neisseria gonorrhoeae* (NG), RNA from *Trichomonas vaginalis* (TV), and RNA from *Mycoplasma genitalium* (MG), to aid in the diagnosis of disease(s) caused by infection from these organisms.

This assay may be used to test the following specimens: **clinician-collected and patient-collected vaginal swabs, male and female urine, endocervical swabs, clinician-collected and patient-collected pharyngeal and rectal swabs.**

Note: Only one urine or swab collected in the Alinity *m* multi-collect specimen collection kit is needed for testing all the following by NAAT at the San Francisco Public Health Laboratory: *Mycoplasma genitalium* / *Chlamydia* / *Gonorrhea* / *Trichomonas vaginalis*.

San Francisco Public Health Laboratory Requisition Form:

<https://www.sfgdp.org/wp-content/uploads/2023/10/Lab-Requisition-Form-Updated-10.17.2023.pdf>

Procedures for specimen collection and submission:

1) Specimen Storage

Submit specimen to the laboratory as soon as possible after collection. Specimens can be stored at 2-30°C for 14 days and at -25°C to -15°C for 60 days.

2) Swab Specimens

Avoid touching the blue top of the Alinity *m* Pierceable Cap to prevent potential contamination.

Do NOT expose swab to Transport Buffer prior to collection.

1. Remove sterile swab from wrapper; do not touch swab tip or lay it down on any surface.
2. Collect specimen:
 - **Vaginal Swab:** Insert white tip of swab about 2 inches (5 cm) without touching the skin or labia external to the vagina. Rotate 15 to 30 seconds. When withdrawing do not touch tip of swab to outside of the vagina.
 - **Endocervical Swab:** Insert only the white tip of swab into the endocervical canal and rotate 15 to 30 seconds.
 - **Rectal Swab:** Insert white tip of swab 0.4 to 1 inch (1-2.5 cm) into the anal canal and rotate at least once.
3. Unscrew transport tube cap and immediately place swab into the transport tube with white tip down.
4. Break swab at the scored line on shaft; use care to avoid splashing of contents.
5. Recap transport tube and ensure cap seals tightly.
6. Label transport tube with sample identification information and include date of collection.

3) Urine Specimens

1. Patient should not have urinated for at least one hour prior to sample collection.
2. Using a urine collection cup, patient should collect the first 20 to 30 mL of voided urine (the first part of the stream).
3. Unscrew transport tube cap and use the disposable transfer pipette to transfer urine from the collection cup to transport tube.
4. Fill transport tube with urine until liquid falls within the clear fill window. Do not overfill or a new transport tube should be used.
5. Recap transport tube and ensure cap seals tightly.
6. Label transport tube with sample identification information and include date of collection. Do not block fill window with label.

Notes on specimen collection:

- The fluids that are contained within the Alinity *m* multi-collect tubes act as a preservative and a cell lysis buffer for specimens. Urine specimens with a final volume higher than the marked fill area could lead to reduced sensitivity upon testing and will be rejected upon arrival to the laboratory.
- Unprocessed urine specimens submitted in urine collection cups will **always** be rejected upon receipt.
- Alinity *m* multi-collect tubes for specimens, other than urine, that do not have a swab in the tube upon receipt at the laboratory will not be processed. Swabs should remain in the tubes as indication of specimen collection (to prevent the likelihood producing false-negative results).
- The patient identification must match between the specimen tube label and the test request form. Mismatches in identification between specimens and forms will not be tested.

4) Completion of Test Request Form for *Chlamydia trachomatis* TMA

The following information must be included on the test request form, or the specimen will not be processed:

1. The name and address of the ordering clinic
2. The ordering clinician's name and **provider ID number, legible.**
3. The patient's first and last name (or unique identifier).
4. The patient's gender.
5. The patient's date of birth (or age).
6. The test to be performed, i.e. "*Chlamydia trachomatis* NAAT" (this must be indicated on the request form).
7. The source of the specimen.
8. The date of specimen collection.

Request forms that fail to include any of this information cannot be tested (according to testing regulations), and calls cannot be made to the clinic to request this information.

Alternately, for San Francisco Health Network providers, electronic test orders can be utilized in lieu of paper requisition forms.

Results:

The turnaround time for specimen testing is 7 business days (Monday through Friday) from specimen receipt, however, results are usually made available within 1-3 business days. If you would like to expedite a specimen for testing, please contact the laboratory directly (see contact information above), and we will do our best to expedite the testing of a certain specimen.

Specimens resulted as "unsatisfactory" are the result of sometimes unknown qualities of a specimen that caused the testing machine to reject the specimen in duplicate. The most frequent causes of assay rejection by the machine, which lead to "unsatisfactory" results are: too low of volume in the Alinity *m* multi-collect tube, caused by a spilling or pouring out of fluid volume during specimen collection; and crystallized substances in urine specimens that we were unable to dissolve upon warming of specimens. Please recollect a specimen in these instances.

Specimens resulted as "inconclusive" were retested and found to be inconclusive for the presence of internal control (IC) and/or cellular control (CC) RNA. Please resubmit a specimen for testing.

Limitations:

- FOR IN VITRO DIAGNOSTIC USE
- Optimal performance of this kit requires appropriate specimen collection, handling, preparation, and storage (refer to the SPECIMEN COLLECTION PROCEDURES section of the package insert).
- The collection of vaginal samples from pregnant women using the Alinity *m* multi-Collect Specimen Collection Kit should be conducted by an obstetrical provider or family physician.
- Vaginal swab sampling is not designed to replace cervical exams for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use the self-collected vaginal swab specimen as a replacement for a pelvic exam.
- The self-collected vaginal swab specimen application is limited to health care facilities where support and counseling is available to explain the procedures and precautions.
- Results from the Alinity *m Chlamydia trachomatis* assay should be interpreted in conjunction with other clinical data available to the clinician.
- Performance of the assay has not been evaluated in patients less than 14 years of age.

Updated: 11/17/2023