Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1100319	03/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mister Labs, Llc	1600 Wallace Drive, Suite 110, Carrollton, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced validation survey of the laboratory was completed on 03/17-3/18 //2026. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, laboratory's establishment studies, laboratory volume records, and confirmed in staff interview, the laboratory failed to ensure complete establishment studies were performed when the laboratory introduced a modified FDA test into the laboratory test systems for one of one specimen type (pooled urine, oropharyngeal and anorectal swabs) on the Roche cobas 8800 analyzer. Findings included: 1. Review of the laboratory's policy titled "Roche Cobas 8800 CT/NG SOP" stated: "Purpose To describe the Roche cobas 8800 system procedure for the testing of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) from urine, oropharyngeal (throat) swab or anorectal (rectal) swab specimens either individually or all pooled. Scope/Applicability ... Pooling samples

enables testing from multiple anatomical sites, improving the detection of these infections. Urine, oropharyngeal (throat) swab or anorectal (rectal) swab specimens will either be ran individually or pooled." 2. Review of the manufacturer's instructions for use "cobas CT/NG" stated: "Specimen collection, transport, and storage ... Specimen collection Endocervical swab specimens collected with the cobas PCR Media Dual Swab Sample Kit, vaginal swab specimens, anorectal swab specimens and oropharyngeal swab specimens collected with either the cobas PCR Media Uni Swab Sample Kit or cobas PCR Media Dual Swab Sample Kit, male and female urine collected with the cobas PCR Urine Sample Kit and cervical specimens collected in PreservCyt Solution have been validated for use with cobas CT/NG (see Table 11 for a list of all collection kits). Follow the instructions for collecting all swab and urine specimens in their respective collection kit IFU ... Procedural limitations ... cobas CT /NG has only been validated for use with male and female urine, clinician-instructed self-collected vaginal swab specimens, clinician-collected vaginal swab specimens, anorectal swab specimens, oropharyngeal swab specimens and endocervical swab specimens, all collected in cobas PCR Media (Roche Molecular Systems, Inc.) and cervical specimens collected in PreservCyt Solution. Assay performance has not been validated for use with other collection media and/or specimen types." The manufacturer's instructions for use did NOT specify pooled urine, oropharyngeal and anorectal swabs as an approved specimen type for the Roche cobas 8800 analyzer. The laboratory modified the FDA approved test system to include CT/NG analysis on pooled urine, oropharyngeal and anorectal swab specimens. 3. A review of the laboratory's establishment studies on the cobas 8800 analyzer revealed the following: In May 2025 establishment studies were performed on the cobas 8800 analyzer for the CT/NG analytes. Further review of the studies revealed the laboratory failed to document establishment of performance specifications on pooled urine, oropharyngeal and anorectal swab specimens for the modified FDA-approved test system that included the following: a) accuracy - The study indicated the use of: "Non-Pooled CT /NG Urine Samples" "Pooled CT/NG Urine Samples" "Non-Pooled CT/NG Swab Samples" "Pooled CT/NG Swab Samples" The "pooled urine" samples failed to indicate if oropharyngeal or anorectal specimens were included in the pooling. The "pooled swab" samples failed to indicate if the type of specimen, oropharyngeal or anorectal were included in the pooling. The accuracy study failed to include a combined pooled specimen that included urine, oropharyngeal and anorectal swabs. b) precision - The study indicated the use of "CT/NG Verification Panel + Urine (Not Spiked) + PCR Media (Not Spiked)" as the specimen type. The precision study failed to include a combined pooled specimen that included urine, oropharyngeal and anorectal swabs. c) sensitivity- The study included the following specimens: "Pooled CT+NG: PCR Media (Spiked) + Urine (Not Spiked) + PCR Media (Not Spiked)" "Pooled CT+NG: PCR Media (Not Spiked) + Urine (Spiked) + PCR Media (Not Spiked)" "Non-Pooled CT+NG: PCR Media (Spiked)" "Non-Pooled CT+NG: Urine (Spiked)" The "pooled" specimens failed to indicate if the type of specimen, oropharyngeal or anorectal were included in the pooling. The sensitivity study failed to include a combined pooled specimen that included urine, oropharyngeal and anorectal swabs. d) specificity/interfering substances - No specificity study to include interfering substances with a combined pooled specimen that included urine, oropharyngeal and anorectal swabs were performed by the laboratory. 4. On 03/17 /2026 at 1:53 p.m. in the conference room, the laboratory was asked to provide documentation of the inclusion of oropharyngeal and anorectal specimen types in the studies, and none were provided. 5. A review of the CT/NG volume records revealed the laboratory performed 66,033 tests from June 2025 through December 2025. 6. During a phone interview in the conference room on 03/17/2026 at 1:53 p.m., the technical supervisor confirmed that the laboratory failed to ensure complete

	establishment studies were performed when the laboratory introduced a modified FDA test into the laboratory test systems for one of one specimen type (pooled urine, oropharyngeal and anorectal swabs) on the Roche cobas 8800 analyzer. Word Key: CT- Chlamydia trachomatis NG- Neisseria gonorrhoeae SOP- standard operating procedures FDA- Food and Drug Administration PCR- polymerase chain reaction
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on random review of patient final reports, patient requisitions, and confirmed in staff interview, the laboratory failed to ensure the final test report reflected the correct age for five of ten patient reports reviewed from October 2025. Findings included: 1. Random review of patient final reports and corresponding patient requisitions from October 2025 revealed discrepancies in the age of the patient on the final report. Patient ID: 680881 Final report date of birth: 11/14/1997; age: 27 years Requisition date of birth: 11/14/1997; age 28 years Patient ID: 390897 Final report date of birth:10 /29/1996; age: 28 years Requisition date of birth: 10/29/1996; age 29 years Patient ID: 679787 Final report date of birth: 02/25/1986; age: 39 years Requisition date of birth: 02/25/1986; age: 40 years Patient ID: 8802 Final report date of birth: 11/27/1981; age: 43years Requisition date of birth: 11/27/1981; age 44years Patient ID: 321119 Final report date of birth: 11/05/1988; age: 36 years Requisition date of birth: 11/05/1988; age 37 years 2. During an interview on 03/18/2026 at 12:26 p.m. in the conference room, the quality representative, after a review of records, confirmed the laboratory failed to ensure the final test report reflected the correct age for five of ten patient reports reviewed from October 2025.