Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2089920	02/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lone Star Tox Screen	801 W Road To Six Flags St Suite 117, Arlington, 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 initial survey was performed from 02/07/2023 to 02/08/2023. The laboratory was found to be NOT in compliance with the CLIA regulations. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F. R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; Laboratory Director Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation, review of laboratory records from 2023 and confirmed in interview, the laboratory failed to establish a uni-directional workflow for the molecular amplification that included a separate area for specimen preparation and reagent preparation for one of one test: STI (sexual transmitted infection) testing using PCR (polymerase chain reaction) on the Applied Biosystems Quant Studio analyzer. Findings were: 1. Surveyor observed on 02/07/2023 at 1510 hours in the laboratory, testing person #1 processed reagents, patient specimens, and control material in the same workbench (#2). No change in gloves and/or cleaning of the workbench in between were observed. 2. No policies to minimize contamination or wipe tests were available for review. 3. Review of the 02/07/2023 run report revealed a NTC (no template control) with a positive result for one organism: Atopobium vaginae. Cross

	refer to D5425. 4. Review of the 02/07/2023 run report confirmed the laboratory ran and reported the following four specimens: 2023002114 2023002115 2023002116 2023002117 5. An interview with the general supervisor on 02/07/2023 at 1525 hours confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory records submitted at time of survey, laboratory policy, laboratory proficiency testing records, and confirmed in interview, the laboratory failed to verify the accuracy of non-regulated analytes for the STI PCR panel at least twice annually for 1 of 1 testing events in 2022. The findings include: 1. Review of the CMS-116 form revealed the laboratory performed laboratory developed STI PCR panels. 2. Review of laboratory records submitted at time of survey revealed the STI PCR Panel tested for the following 47 targets: Atropium vaginae BVAB2 Candida albicans Candida dubliniensis Candida glabrata Candida parapsilosis Candida tropicalis Chlamydia trachomatis Clavispora lustaniae CMV_Human cytomegalovirus Gardnerella vaginalis Haemophilus ducreyi HSV 1 HSV 2 Lactobacillus crispatus Lactobacillus jensenii Lymphogranulona venereum Megasphaera 1 Megasphaera 2 Mobiluncus curtisii Mobiluncus mulieris Mycoplasma genitalium Nesseria gonorrhoeae Pichia kudriavzevii Steptococcus agalactiae Streptococcus pyogenes Treponema pallidum Trichomonas vaginalis Ureaplasma parvum Ureaplasma urealyticum Varicella zoster/Human alphaherpesvirus Bacteria ermB Candida kefyr HPV 16 HPV 18 HPV 31 HPV 33 HPV 35 HPV 39 HPV 45 HPV 51 HPV 52 HPV 56 HPV 58 HPV 59 HPV 66 HPV 68 3. Review of the laboratory policy titled "QM-1.2 Atlas Genomics Quality Assurance Program" revealed: "Assessments 1. Assessments include processes and procedures to support external regulatory audits, internal regulatory/quality system audits, to ensure regulatory compliance and to promote continuous improvement. Assessments also include external and alternative proficiency testing (PT). Alternative PT is in place for those analytes where PT programs are not offered commercially. There is documented evaluation and review of performance in all proficiency testing. Multi-systems agreements are in place for procedures common among sites, if applicable. There is documented evidence of Laboratory Management review of internal audit findings and Executive Management review of PT and multi-systems agreement results and external audit findings." 4. Review of the laboratory's proficiency testing records for 2022 revealed no documentation of twice annual accuracy assessments for the above non-regulated analytes for 1 of 1 testing event in 2022. 5. During an interview on 02/07/2023 at 09: 30 a.m., the surveyor asked General Supervisor (GS)- 1 when the laboratory began performing STI PCR panels, GS-1 stated they began performing STI PCR panels in June 2022. The surveyor requested documentation of accuracy assessments for the non-regulated analytes on the PCR panel for 2022. None were provided. This confirmed the above findings. Key: STI PCR- Sexually transmitted infection polymerase chain reaction BVAB2- Bacterial vaginosis associated bacterium 2 CMV- Cytomegalovirus HSV- Herpes simplex virus ermB- Erythromycin resistance gene B HPV- Human papillomavirus

D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, review of the laboratory's preanalytical studies, review of the laboratory and patient records, the laboratory failed to meet the requirements for preanalytical systems, as evidenced by: 1. The laboratory failed to establish the preanalytical requirements for the STI (Sexually transmitted Infections) panel using one of two specimen swabs (Aptima multitest swab). Refer to D5311. 2. The laboratory failed to have written instructions available to the laboratory's clients that included information on specimen collection, specimen storage and preservation, conditions for specimen transportation, and specimen acceptability and rejection for one of one test: STI (Sexually transmitted Infections) panel. Refer to D5317.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from October 2022 to January 2023, manufacturer's instructions, and confirmed in interview, the laboratory failed to establish the preanalytical requirements for the STI (Sexually transmitted Infections) panel using one of two specimen swabs (Aptima multitest swab). A) Specimen source: vaginal/rectal; vaginal/vulvovaginal; cervical B) Specimen stability Findings were: 1. According to laboratory records, the laboratory performed STI Panel for the qualitative detection of the following 47 organisms on Aptima multitest swab for the following three specimen sources: vaginal/rectal; vaginal/vulvovaginal; cervical. CMV Gardnerella vaginalis HSV 1 HSV 2 Haemophilus ducreyi Treponema pallidum Streptococcus pyogenes Bacteria ermB Candida dubliniensis Candida glabrata Candida kefyr Pichia kudriavzevii Clavispora lusitaniae Candida parapsilosis Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Candida albicans Candida tropicalis Mycoplasma genitalium Ureaplasma parvum Ureaplasma urealyticum Varicella Zoster Streptococcus agalactiae Atopobium vaginae BVAB2 Lactobacillus crispatus Lactobacillus jensenii CT/Lymphogranuloma venereum Megasphaera 1 Megasphaera 2 Mobiluncus mulieris Mobiluncus curtisii HPV16 HPV18 HPV31 HPV33 HPV35 HPV39 HPV45 HPV51 HPV52 HPV56 HPV58 HPV59 HPV66 HPV68 2. Review of the package insert for the Aptima Multitest

	Swab Specimen Collection Kit (AW-26253-001 Rev. 001) under intended use stated "the The Aptima Multitest Swab Specimen Collection Kit is intended to be used for collection of the following swab specimen types: vaginal, rectal, throat, penile meatal, and lesions," and under limitations, it stated "Use this collection kit only with Aptima assays and other Hologic products. Performance has not been established with other products. Use of the Multitest swab for patient-collected vaginal specimen collection is not designed to replace cervical exams and endocervical samples 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" A) Specimen source: vaginal/rectal; vaginal/vulvovaginal; cervical 3. No documentation of the preanalytical studies were available for review for the Aptima Multitest swab to include three of three specimen sources: vaginal/rectal; vaginal/vulvovaginal; cervical. Cross refer to D5423. B) Specimen stability 4. No documentation of the preanalytical studies were available for review for the Aptima Multitest swab to include the specimen stability. Cross refer to D5423 5. Random review of the laboratory records from November 2022 to January 2023 confirmed the laboratory performed the following six STI testing using the Aptima Multitest Swab. Accession Number: T2022003805-PAP Specimen source: vaginal/rectal Date: 12/06 /2022 Accession Number: T2023002091-PAP Specimen source: vaginal/vulvovaginal Date: 01/19/2023 Accession Number: T2023002092-PAP Specimen source: vaginal /vulvovaginal Date: 01/19/2023 Accession Number: T2023002095-PAP Specimen source: cervical Date: 01/19/2023 Accession Number: T2022003803-PAP Specimen source: cervical Date: 12/06/2022 Accession Number: T2022003801-PAP Specimen source: cervical Date: 12/06/2022 6. An interview with the chief regulatory officer via TEAMS video call on 02/08/2023 at 1025 hours confirmed the above findings. She stated that a bridging study was performed, but it did not include the preanalytical requirements for specimen source nor stability. Key: CMV- Cytomegalovirus HSV- Herpes simplex virus ermB- erythromycin resistance gene B BVAB2- Bacterial vaginosis associated bacterium 2 CT- Chlamydia trachomatis HPV- Human papillomavirus
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory policies, review of patient test records from 2022 to 2023, and confirmed in interview, the laboratory failed to have written instructions available to the laboratory's clients that included information on specimen collection, specimen storage and preservation, conditions for specimen transportation, and specimen acceptability and rejection for one of one test: STI (Sexually transmitted Infections) panel. Findings included: 1. No documentation of written instructions for the specimen collection, specimen storage and preservation, specimen acceptability and rejection, and transport (with specified acceptable temperature range) were available for review for one of one test: STI (Sexually transmitted Infections) panel. 2. Per the general supervisor, the laboratory began testing for STI in June 2022. Review of the CMS-116 form revealed an annual volume of 354,500. 3. An interview with the general supervisor on 02/08/2023 at 0930 hours in the break room confirmed the above findings. Key: CMS-Centers for Medicare and Medicaid

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policies, laboratory establishment records, quality control records, patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems as evidenced by: 1. The laboratory failed to document complete establishment studies for one of one lab developed test: the STI (Sexually transmitted Infections) panel using one of two specimen swabs (Aptima multitest swab). Refer to D5423. 2. The laboratory failed to establish a mechanism to detect cross contamination of patient samples for six of six patient runs reviewed. Refer to D5425. 3. The laboratory failed to establish control procedures that could detect immediate errors for two of six patient runs reviewed for STI (Sexually transmitted Infections) panel testing. Refer to D5441. 4. The laboratory failed to document positive and negative control testing for six of six patient runs reviewed for STI (Sexually transmitted Infections) panel testing. Refer to D5449.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(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: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory records and patient test records from October 2022 to January 2023, manufacturer's instructions, and confirmed in interview, the laboratory failed to document complete establishment studies for one of one lab developed test: the STI (Sexually transmitted Infections) panel using one of two specimen swabs (Aptima multitest swab). Findings were: 1. According to laboratory records, the laboratory performed STI Panel for the qualitative detection of the following 47 organisms on Aptima multitest swab for the following three specimen sources: vaginal/rectal; vaginal/vulvovaginal; cervical. CMV Gardnerella vaginalis HSV 1 HSV 2 Haemophilus ducreyi Treponema pallidum Streptococcus pyogenes Bacteria ermB Candida dubliniensis Candida glabrata Candida kefyr Pichia kudriavzevii Clavispora lusitaniae Candida parapsilosis Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Candida albicans Candida tropicalis

	Mycoplasma genitalium Ureaplasma parvum Ureaplasma urealyticum Varicella Zoster Streptococcus agalactiae Atopobium vaginae BVAB2 Lactobacillus crispatus Lactobacillus jensenii CT/Lymphogranuloma venereum Megasphaera 1 Megasphaera 2 Mobiluncus mulieris Mobiluncus curtisii HPV16 HPV18 HPV31 HPV33 HPV35 HPV39 HPV45 HPV51 HPV52 HPV56 HPV58 HPV59 HPV66 HPV68 2. Per laboratory policy Assay Design and Validation (QM-5.21), it stated under analytical validation "analytical validation is required for all modified FDA-approved or non-FDA cleared tests (Laboratory developed tests). The following performance characteristics must be established prior to assay implementation: -accuracy -precision -analytic sensitivity -analytic specificity -specimen stability -carryover 3. No documentation of the precision, analytic sensitivity, analytic specificity, specimen stability (cross refer to D5311) and carryover were available for review for the STI panel using the Aptima multitest swab. 4. Random review of the laboratory records from November 2022 to January 2023 confirmed the laboratory performed the following six STI panels using the Aptima Multitest Swab. Accession Number: T2022003805-PAP Specimen source: vaginal/rectal Date: 12/06/2022 Accession Number: T2023002091-PAP Specimen source: vaginal/vulvovaginal Date: 01/19 /2023 Accession Number: T2023002092-PAP Specimen source: vaginal/vulvovaginal Date: 01/19/2023 Accession Number: T2023002095-PAP Specimen source: cervical Date: 01/19/2023 Accession Number: T2022003803-PAP Specimen source: cervical Date: 12/06/2022 Accession Number: T2022003801-PAP Specimen source: cervical Date: 12/06/2022 5. An interview with the chief regulatory officer via TEAMS video call on 02/08/2023 at 1015 hours confirmed the above findings. Key: CMV-Cytomegalovirus HSV- Herpes simplex virus ermB- erythromycin resistance gene B BVAB2- Bacterial vaginosis associated bacterium 2 CT- Chlamydia trachomatis HPV- Human papillomavirus
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from August 2022 to February 2023, and confirmed in interview, the laboratory failed to establish a mechanism to detect cross contamination of patient samples for six of six patient runs reviewed (08/03/2022; 10/06/2022; 11/15/2022; 12/08/2022; 01/26/2023; 02/07 /2023). Findings included: 1. Random review of patient runs from August 2022 to February 2023 confirmed the laboratory included a NTC (no template control) which was only molecular grade water for five of six patient runs reviewed. Five of the six patient runs showed amplification for the following organism(s). 10/06/2022: Atopobium vaginae 11/15/2022: Atopobium vaginae 12/08/2022: Atopobium vaginae; Megasphaera 1 01/26/2023: Atopobium vaginae 02/07/2023: Atopobium vaginae 2. Random review of patient test runs from August 2022 to February 2023 confirmed the laboratory did NOT include a NTC (no template control) for one of six patient runs reviewed (08/03/2022). 3. The laboratory analyzed and reported the following 22 patients from the above patient runs. 08/03/2022: 2022003248; 2022003249; 2022003250; 2022003251 10/06/2022: 2022003530; 2022003531; 2022003532; 2022003533 11/15/2022: 2022003686; 2022003687 12/08/2022: 2022003806; 2022003807; 2022003808; 2022003809 01/26/2023: 2023002102;

	2023002103; 2023002104; 2023002105 02/07/2023: 2023002114; 2023002115; 2023002116; 2023002117 4. An interview with the technical supervisor on 02/08 /2023 at 1040 hours via TEAMS video call confirmed the above findings. She stated that she was aware that there were contamination and they were actively working on it. An interview with the lab director at 02/08/2023 at 1240 hours confirmed that he was aware of the contamination but that he would still call a patient specimen detected for the same organism because the amplification was greater than the contaminant.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient and test records from August 2022 to February 2023 and confirmed in interview, the laboratory failed to establish control procedures that could detect immediate errors for two of six patient runs reviewed for STI (Sexually transmitted Infections) panel testing. Findings included: 1. According to laboratory records, the laboratory began performing STI Panel for the qualitative detection of the following 47 organisms in June 2022. CMV Gardnerella vaginalis HSV 1 HSV 2 Haemophilus ducreyi Treponema pallidum Streptococcus pyogenes Bacteria ermB Candida dubliniensis Candida glabrata Candida kefyr Pichia kudriavzevii Clavispora lusitaniae Candida parapsilosis Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Candida albicans Candida tropicalis Mycoplasma genitalium Ureaplasma parvum Ureaplasma urealyticum Varicella Zoster Streptococcus agalactiae Atopobium vaginae BVAB2 Lactobacillus crispatus Lactobacillus jensenii CT/Lymphogranuloma venereum Megasphaera 1 Megasphaera 2 Mobiluncus mulieris Mobiluncus curtisii HPV16 HPV18 HPV31 HPV33 HPV35 HPV39 HPV45 HPV51 HPV52 HPV56 HPV58 HPV59 HPV66 HPV68 2. Laboratory patient run records from August 2022 to February 2023 confirmed the laboratory began performing Positive quality control (Taqman Comprehensive Microbiota Control) testing in January 2023. 3. Random review of the patient runs in January 2023 to February 2023 showed 'undetermined' for two of two patient runs reviewed (01/26/2023 and 02/07 /2023). 01/26/2023 (16 of 47 targets) CMV HSV 2 Treponema pallidum Candida glabrata Candida parapsilosis Mycoplasma genitalium Ureaplasma urealyticum Mobiluncus curtisii HPV16 HPV31 HPV35 HPV39 HPV51 HPV56 HPV58 HPV68 02/07/2023 (25 of 47 targets) Gardnerella vaginalis HSV 1 Haemophilus ducreyi Candida glabrata Candida kefyr Clavispora lusitaniae Candida parapsilosis Neisseria gonorrhoeae Trichomonas vaginalis Candida tropicalis Mycoplasma genitalium Ureaplasma parvum Ureaplasma urealyticum Varicella Zoster BVAB2 Lactobacillus crispatus Megasphaera 1 HPV18 HPV35 HPV39 HPV51 HPV56 HPV58 HPV59 HPV66 4. The laboratory analyzed and reported the following eight patients from the above patient runs. 01/26/2023: 2023002102; 2023002103; 2023002104; 2023002105

	02/07/2023: 2023002114; 2023002115; 2023002116; 2023002117 5. An interview with the chief regulatory officer on 02/08/2023 via TEAMS video call at 1020 hours confirmed the above findings. She stated that the above positive quality control were around the cutoff; therefore, would sometimes turn negative and was still acceptable. Key: CMV- Cytomegalovirus HSV- Herpes simplex virus ermB- erythromycin resistance gene B BVAB2- Bacterial vaginosis associated bacterium 2 CT- Chlamydia trachomatis HPV- Human papillomavirus
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient and test records from August 2022 to February 2023 and confirmed in interview, the laboratory failed to document positive and negative control testing for six of six patient runs reviewed for STI (Sexually transmitted Infections) panel testing. Findings included: 1. According to laboratory records, the laboratory began performing STI Panel for the qualitative detection of the following 47 organisms in June 2022. CMV Gardnerella vaginalis HSV 1 HSV 2 Haemophilus ducreyi Treponema pallidum Streptococcus pyogenes Bacteria ermB Candida dubliniensis Candida glabrata Candida kefyr Pichia kudriavzevii Clavispora lusitaniae Candida parapsilosis Chlamydia trachomatis Neisseria gonorrhoeae Trichomonas vaginalis Candida albicans Candida tropicalis Mycoplasma genitalium Ureaplasma parvum Ureaplasma urealyticum Varicella Zoster Streptococcus agalactiae Atopobium vaginae BVAB2 Lactobacillus crispatus Lactobacillus jensenii CT /Lymphogranuloma venereum Megasphaera 1 Megasphaera 2 Mobiluncus mulieris Mobiluncus curtisii HPV16 HPV18 HPV31 HPV33 HPV35 HPV39 HPV45 HPV51 HPV52 HPV56 HPV58 HPV59 HPV66 HPV68 2. No documentation of a negative control for the above organisms for two of six patient runs reviewed (01/26/2023 and 02/07/2023) was available for review. 3. No documentation of positive and negative control for the above organisms for four of six patient runs reviewed (08/03/2022; 10 /06/2022; 11/15/2022; 12/08/2022). 4. The laboratory analyzed and reported the following 22 patients from the above patient runs. 08/03/2022: 2022003248; 2022003249; 2022003250; 2022003251 10/06/2022: 2022003530; 2022003531; 2022003532; 2022003533 11/15/2022: 2022003686; 2022003687 12/08/2022: 2022003806; 2022003807; 2022003808; 2022003809 01/26/2023: 2023002102; 2023002103; 2023002104; 2023002105 02/07/2023: 2023002114; 2023002115; 2023002116; 2023002117 5. An interview with the chief regulatory officer on 02/08 /2023 via TEAMS video call at 1020 hours confirmed the above findings. Key: CMV- Cytomegalovirus HSV- Herpes simplex virus ermB- erythromycin resistance gene B BVAB2- Bacterial vaginosis associated bacterium 2 CT- Chlamydia trachomatis HPV- Human papillomavirus
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient records and confirmed in interview, the laboratory failed to include the name and address of the laboratory where the STI PCR test was performed for 25 of 25 patients in 2022 and 2023 (random sampling). The findings include: 1. Review of patient records from 2022 and 2023 revealed the following 25 final reports (random sampling) that did not include the name and address of the laboratory where the STI PCR test was performed: 06/30/2022 Accession #'s: 20220031111-PAP, 2022003112-PAP 07/02/2022 Accession #'s: 2022003122-PAP, 2022003123-PAP, 2022003124-PAP 08/03/2022 Accession #'s: 2022003253-PAP, 2022003255-PAP, 2022003254-PAP 08/05/2022 Accession #'s: 2022003256-PAP, 2022003257-PAP 10 /06/2022 Accession #'s: T2022003530-PAP, T2022003531-PAP, T2022003532-PAP, T2022003533-PAP 10/14/2022 Accession #: T2022003552-PAP 11/14/2022 Accession #'s: T2022003682-PAP, T2022003684-PAP, T2022003685-PAP, T2022003683-PAP 12/08/2022 Accession #'s: T2022003812-PAP, T2022003811-PAP, T2022003810-PAP, T2022003809-PAP, T2022003808-PAP 01/26/2023 Accession #: T2023002105-PAP 2. During an interview on 02/08/2023 at 09:15 a.m., General Supervisor (GS)-1 confirmed the above findings. Key: STI PCR- Sexually transmitted infection polymerase chain reaction
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient records and confirmed in interview, the laboratory failed to ensure STI PCR reference ranges were included on 25 of 25 final patient reports in 2022 and 2023 (random sampling). The findings include: 1. Review of patient records from 2022 and 2023 revealed the following 25 final reports (random sampling) that did not include STI PCR reference ranges: 06/30/2022 Accession #'s: 20220031111-PAP, 2022003112-PAP 07/02/2022 Accession #'s: 2022003122-PAP, 2022003123-PAP, 2022003124-PAP 08/03/2022 Accession #'s: 2022003253-PAP, 2022003255-PAP, 2022003254-PAP 08/05/2022 Accession #'s: 2022003256-PAP, 2022003257-PAP 10/06/2022 Accession #'s: T2022003530-PAP, T2022003531-PAP, T2022003532-PAP, T2022003533-PAP 10/14/2022 Accession #: T2022003552-PAP 11/14/2022 Accession #'s: T2022003682-PAP, T2022003684-PAP, T2022003685-PAP, T2022003683-PAP 12/08/2022 Accession #'s: T2022003812-PAP, T2022003811-PAP, T2022003810-PAP, T2022003809-PAP, T2022003808-PAP 01 /26/2023 Accession #: T2023002105-PAP 2. During an interview on 02/08/2023 at 12: 15 p.m. the General Supervisor (GS)-1 after review of patient final reports, confirmed reference ranges for STI PCR were not present on the final reports. This confirmed

	the above findings. Key: STI PCR- Sexually transmitted infection polymerase chain reaction
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management and direction for high complexity testing. The findings were: 1. The laboratory director failed to ensure establishment studies were complete. Refer to D6082. 2. The laboratory director failed to ensure a quality control program was established and followed. Refer to D6093. 3. The laboratory director failed to specify, in writing, responsibilities and duties for 2 of 3 testing persons performing high complexity testing. Refer to D6107.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies for its lab developed test and confirmed in staff interview, the laboratory director failed to ensure the studies were complete prior to patient testing. Refer to D5423.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records and staff interview, the laboratory director failed to ensure a quality control plan was established and followed for high complexity testing. Refer to D5425, D5441, D5449.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which

	examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)- 209 form, personnel records, and confirmed in interview, the laboratory director failed to specify, in writing, responsibilities and duties for 2 of 3 testing persons (TP) performing high complexity testing. Findings included: 1. Review of the CMS-209 form revealed TP-1 and TP-3 were listed to perform high complexity testing. 2. Review of personnel records revealed TP-1 and TP-3 did NOT have a testing personnel delegation of duties/job description. The laboratory director failed to specify, in writing, responsibilities and duties for TP-1 and TP-3. 3. During the exit interview on 02/08/2019 at 2:30 p.m., laboratory representatives confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services (CMS)- 209 form, laboratory policies, personnel records, and interview with staff, the Technical Supervisor (TS) failed to perform semi-annual competency evaluations for 3 of 3 testing persons (TP-1, TP-2, TP-3) for the high complexity testing in the specialty of Microbiology in 2022. Findings included: 1. Review of the CMS- 209 form revealed TP-1, TP-2 and TP-3 were listed to perform high complexity testing. 2. Review of the laboratory's "Employee Competency Assessment" policy revealed: "POLICY: General Policies: 1. Competency assessments (CA) are designed to provide a consistent objective measure of reviewing performance and giving feedback on specific job tasks. The tasks evaluated will vary depending on the tasks assigned to the employee and the QA/QC records they must maintain. 2. Competency assessments are required for all technical personnel handling patient specimens." 3. Review of laboratory personnel records for TP-1 revealed a six-month competency assessment performed on 06/1/2021. The semi-annual competency was performed by the general supervisor (GS-1) and NOT the TS. Review of laboratory personnel records for TP-2 revealed a six-month competency assessment performed on 01/16/2023. The semi-annual competency was performed by the general supervisor (GS-2) and NOT the TS. Review of laboratory personnel records for TP-3 revealed a six-month competency assessment on 04/25/2021. Further review of records revealed no other semiannual competency assessments for TP-3 (due 10/2021). The TS failed to perform annual competency assessments for TP-1, TP-2 and TP-3. 3. During the exit interview on 02 /08/2019 at 2:30 p.m., laboratory representatives confirmed the above findings.