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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2074140 | (X3) Date Survey Completed 01/27/2021 |
| Name of Provider or Supplier Diagnostic Affiliates Of Northeast Hou, Llc | Street Address, City, State 22001 Northpark Dr Suite 221, Kingwood, 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 | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. |
| D5217 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2020, and staff interview, it was revealed that the laboratory failed to have documentation of performing twice annual accuracy assessments in 2020 for 7 of 34 unregulated analytes tested on the Applied Biosystems Quant Studio 12K Flex analyzer. Findings include: 1. A review laboratory's policy titled 'Proficiency Testing' revealed the following: "Proficiency testing (PT) must be performed for each analyte being reported by the laboratory, whether it be a regulated or unregulated analyte...the accuracy of all analytes must be tested at least twice per year." 2. A review of the laboratory's College of American Pathologists proficiency testing records revealed the laboratory failed to perform twice annual accuracy assessments in 2020 for the following 7 analytes tested on the Applied Biosystems Quant Studio 12K Flex analyzer: - Mycoplasma Hominis - Megasphaera Species 1 - Megasphaera Species 2 - Ureaplasma Urealyticum - Haemophilus Ducreyi - Mycoplasma Genitalium - Treponema Pallidum 3. The laboratory was asked to provide documentation of assessing the accuracy, twice annually, for the above listed analytes. No</p> |

documentation was provided. 4. An interview with technical supervisor #1 (as indicated on the CMS 209 form, signed by the laboratory director on 1/25/21) on 1/26/21 at 1:00 p.m. in the conference room, after review of the records, confirmed the above findings.

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:

I. Based on review of the laboratory records, patient test records from October 2020 to January 2021 and confirmed in interview, the laboratory failed to document complete preanalytical studies for the Vaginits Open Array Panel with Copan eSwab. A) temperature B) specimen stability Findings were: 1. Review of the laboratory records revealed the laboratory performed Vaginits Open Array Panel for the qualitative detection of the following 34 organisms on vaginal Copan eSwabs. Atopobium Vaginae BVAB2 Megasphaera Species 1 Megasphaera Species 2 Mycoplasma Hominis Ureaplasma Urealyticum Gardnerella vaginalis Bacteroides Fragilis Lactobacillus Crispatus Prevotella Bivia Mobiluncus Curtisil Mobiluncus Mulieris Lactobacillus Gasseri Lactobacillus Iners Lactobacillus Genitalium Mycoplasma Genitalium Haemophilus Ducreyi Treponema Pallidum Chlamydia Trachomatis Neisseria Gonorrhoeae Trichomonas Vaginalis Herpes Simplex 1 Herpes Simplex 2 Enterococcus Faecalis Escherichia Coli Staphylococcus Aureus Streptococcus Agalactiae Candida Tropicalis Candida Albicans Candida Lusitaniae Candida Dubliensis Candida Parapsilosis Candida Glabrata Candida Krusel 2. Review of the laboratory client service manual Instructions for Use for the Vaginal Panel Specimen Collection under swab storage and transport revealed stability at 2-30 C for 8 days and 2-8C for 14 days. 3. Review of the laboratory policy Specimen Hold, Rejection, Send Out, and Missing information (GEN-012.00) under Rejected Specimens "specimen is outside of established stability requirements (e.g. too old) Women's Health Specimens [vaginal panel specimen] are stable for 19 days at 4 C." A) temperature 4. Review of the laboratory preanalytical studies revealed no documentation of stability temperature studies to include 2-30 C for 8 days or 2-8 C for 14 days or 19 days at 4 C. B) specimen stability 5. Review of the laboratory preanalytical studies revealed no documentation of stability of the presence of 7 of 34 organisms for any temperature range assessed (4 C or -20 C). Megasphaera Species 2 Mobiluncus Mulieris Mycoplasma Genitalium Haemophilus Ducreyi Treponema Pallidum Candida Lusitaniae Candida Dubliensis 6. An interview with the technical supervisor on 1/26/21 at 1250 hours in the conference room and confirmed with one of the lab couriers revealed that all specimens collected are stored in a cooler during transport. No temperature is monitored before, during, or after transport of all specimens. The courier also confirmed that there is no set criteria for "refrigerated" specimens. 7. Random review of the Women's Health Panel testing for the Vaginits Panel from October 2020-January 2021 using the Copan eSwab revealed the following elapsed time in days. accn # collection date run date elapsed time 49777 10/29/2020 10/30/2020 1 52827 11/06/2020 11/11/2020 5 58465 11/18/2020 11/20/2020 2 65947 12/01

/2020 12/03/2020 2 68946 12/07/2020 12/08/2020 1 97800 01/18/2021 01/19/2021 1 96638 01/15/2021 01/19/2021 4 98605 01/19/2021 01/23/2021 4 100157 01/21/2021 01/23/2021 2 83759 12/28/2020 01/01/2021 4 75372 12/15/2020 12/18/2020 3 68996 12/07/2020 12/11/2020 4 75371 12/15/2020 12/18/2020 3 70675 12/09/2020 12/11/2020 2 8. An interview with the technical supervisor #1 on 1/27/21 at 1120 hours in the conference room confirmed the above findings. She agreed that the laboratory should establish the temperature range used in the client service manual. She also acknowledged that the presence of the organism should be used to determine stability.

II. Based on review of the laboratory records, patient test records from December 2020 to January 2021 and confirmed in interview, the laboratory failed to document complete preanalytical studies for the SARS-CoV 2 testing. A) specimen stability and temperature B) specimen transport media Findings were: 1. Review of the laboratory records revealed the laboratory started SARS-CoV 2 testing on 05/2020. 2. Review of the laboratory client service manual Respiratory Specimen Collection Guide under materials revealed 4 acceptable transport media: VTM (viral transport media), MTM (molecular transport media), Liquid amies, or PBS (phosphate buffered saline). 3. Review of the laboratory policy Specimen Hold, Rejection, Send Out, and Missing information (GEN-012.00) under Rejected Specimens "specimen is outside of established stability requirements (e.g. too old) respiratory swabs are stable for 24 hours at room temperature or 14 days at 4 C." A) specimen stability and temperature 4. Review of the laboratory preanalytical studies revealed no documentation of stability temperature studies to include 24 hours at room temperature or 14 days at 4 C. B) specimen transport media 5. Review of the laboratory preanalytical studies revealed no documentation of complete stability studies for 3 of the 4 acceptable transport media: VTM, liquid Amies, and MTM. 6. An interview with the technical supervisor on 1/26/21 at 1250 hours in the conference room and confirmed with one of the lab couriers revealed that all specimens collected are stored in a cooler during transport. No temperature is monitored before, during, or after transport of all specimens. The courier also confirmed that there is no set criteria for "refrigerated" specimens. 7. Random review of the SARS-CoV 2 patient testing from December 2020-January 2021 revealed the laboratory performed 15 patient testing with the following elapsed time in days. All specimen received were nasopharangeal swabs with PBS transport media. accn # collected run date elapsed time 97381 01/18/2021 01/19/2021 1 97378 01/18/2021 01/19/2021 1 97386 01/18/2021 01/19/2021 1 93668 01/12/2021 01/13/2021 1 93693 01/12/2021 01/13/2021 1 94422 01/13/2021 01/14/2021 1 94421 01/13/2021 01/14/2021 1 96946 01/16/2021 01/17/2021 1 93994 01/12/2021 01/13/2021 1 65941 12/01/2020 12/02/2020 1 71873 12/11/2020 12/12/2020 1 72271 12/11/2020 12/12/2020 1 100812 01/22/2021 01/23/2021 1 94510 01/13/2021 01/14/2021 1 95834 01/14/2021 01/15/2021 1 8. An interview with the technical supervisor #1 on 1/27/21 at 1120 hours in the conference room confirmed the above findings. She agreed that the laboratory should establish the temperature range used in the client service manual.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's records, and staff interview it was revealed the

laboratory failed to have documentation of a quality assurance plan to identify and correct problems in preanalytic systems. Refer to D5311

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, patient test records from October 2020 to January 2021 and confirmed in interview, the laboratory failed to document complete establishment studies for for 2 of 2 laboratory developed tests: Vaginits Open Array Panel and SARS-CoV 2 testing. A) Vaginits Open Array Panel B) SARS-CoV 2 Findings were: 1. Review of the laboratory policy Method Validation Plan (GEN-008.0) revealed "a method validation plan/proposal should be created and approved by the laboratory director prior to the start of the validation study. This policy is to be used to create the validation plan, validation specifics may be added or taken out, as appropriate for the test system being validated." 2. Review of the laboratory establishment records for both lab developed tests: Vaginits Open Array Panel and SARS-CoV 2 revealed no documentation of the validation plan/proposal to include the acceptance criteria of all studies performed: precision, accuracy, limit of detection, preanalytical studies, and any other performance characteristics required for test performance for all acceptable specimen types. 3. Random review of the Women's Health Panel testing for the Vaginits Panel from October 2020-January 2021 revealed the laboratory performed 14 patient testing. accn # 49777 52827 58465 65947 68946 97800 96638 98605 100157 83759 75372 68996 75371 70675 4. Random review of the SARS-CoV 2 patient testing from October 2020-January 2021 revealed the laboratory performed 15 patient testing. accn # 97381 97378 97386 93668 93693 94422 94421 96946 93994 65941 71873 72271 100812 94510 95834 5. An interview with the technical supervisor #1 on 1/27/21 at 1230 hours in the conference room confirmed the above findings.

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 records, manufacturer's instructions and confirmed in interview, the laboratory failed to establish and document performance

specifications for their QC (quality control) material used for 2 of 2 laboratory developed tests: Vaginits Open Array Panel and SARS-CoV 2 testing. A) Vaginits Open Array Panel B) SARS-CoV 2 Findings included: A) Vaginits Open Array Panel 1. Review of the laboratory records from October 2020- January 2021 revealed the laboratory performed Vaginits Open Array Panel with the qualitative detection of the following 34 organisms on vaginal Copan eSwabs. Atopobium Vaginae BVAB2 Megasphaera Species 1 Megasphaera Species 2 Mycoplasma Hominis Ureaplasma Urealyticum Gardnerella vaginalis Bacteroides Fragilis Lactobacillus Crispatus Prevotella Bivia Mobiluncus Curtisil Mobiluncus Mulieris Lactobaccillus Gasseri Lactobaccillus Iners Lactobaccillus Genitalium Mycoplasma Genitalium Haemophilus Ducreyi Treponema Pallidum Chlamydia Trachomatis Neisseria Gonorrhoeae Trichomonas Vaginalis Herpes Simplex 1 Herpes Simplex 2 Enterococcus Faecalis Escherichia Coli Staphylococcus Aureus Streptococcus Agalactiae Candida Tropicalis Candida Albicans Candida Lusitaniae Candida Dubliensis Candida Parapsilosis Candida Glabrata Candida Krusel 2. Review of the laboratory records revealed no documentation of the establishment of 3 of 3 quality control (NTC, POSA, POSB) the laboratory used for the Vaginits Open Array Panel. 3. Random review of the Women's Health Panel testing for the Vaginits Panel from October 2020- January 2021 revealed the laboratory performed 14 patient testing using the 3 quality controls (NTC, POSA, POSB). accn # 49777 52827 58465 65947 68946 97800 96638 98605 100157 83759 75372 68996 75371 70675 B) SARS-CoV 2 4. Review of the laboratory records from October 2020-January 2021 revealed the laboratory performed SARS-CoV 2 using 2 quality control (NTC, POS CON). 5. Review of the laboratory records available revealed no documentation of the verification of both quality control above. 6. Random review of the SARS-CoV 2 patient testing from October 2020-January 2021 revealed the laboratory performed 15 patient testing using the 2 quality control (NTC, POS CON). accn # 97381 97378 97386 93668 93693 94422 94421 96946 93994 65941 71873 72271 100812 94510 95834 7. An interview with the technical supervisor on 1/27/21 at 1100 hours in the conference room confirmed the above findings. key: NTC - no template control POSA - positive control POSB - positive control POS CON - positive control

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's records, and staff interview, the laboratory failed to have documentation of a quality assurance plan to monitor and detect errors in the analytic systems. (refer to D5423)