

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2112898	(X3) Date Survey Completed 05/11/2023
Name of Provider or Supplier Star Er,Llc	Street Address, City, State 7007 Indiana Ave, Lubbock, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions, quality control (QC) records, patient testing logs, and interview, the laboratory failed to document the results of the internal procedural controls for the Consult Diagnostics hCG (human chorionic gonadotropin) Urine Test Cassette for 21 of 21 patients tested from 03/04/2023 - 03/19/2023. Findings follow. A. Review of the McKesson Consult Diagnostics hCG Urine Test Cassette, Rev 00 12/15, under Quality Control stated, "Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result..." B. Review of the Laboratory Master Specimen Log from 03/04/2023 - 03/19/2023 showed the documentation of the QC and patient testing logs: and showed 17 out of 21 patients missing the results of the positive procedural control, and 20 out of 21 patients missing the results for the negative procedural control: Date of Service Account # Missing Procedural Control 1. 03/19/2023 22684 Neg 2. 03/14/2023 22588 Neg 3. 03/13/2023 22572 Neg 4. 03/13/2023 22556 Pos & Neg 5. 03/13/2023 22571 Neg 6. 03/12/2023 22521 Pos & Neg 7. 03/11/2023 22504 Neg 8. 03/11/2023 22490 Neg 9. 03</p>

/10/2023 22473 Neg 10. 03/09/2023 22450 Pos & Neg 11. 03/08/2023 22428 Neg 12. 03/08/2023 22434 Pos 13. 03/08/2023 22416 Neg 14. 03/07/2023 22397 Neg 15. 03/07/2023 22392 Neg 16. 03/07/2023 22385 Neg 17. 03/07/2023 22387 Neg 18. 03/07/2023 22383 Neg 19. 03/07/2023 22384 Neg 20. 03/06/2023 22356 Neg 21. 03/05/2023 22333 Neg C. Interview with Technical Consultant #2, as listed on the CMS Form 209, on May 11, 2023 at 1835 hours in the laboratory acknowledged they should be documenting the internal controls. Interview with testing personnel #8 on May 11, 2023 at 1900 hours in the break room acknowledged he was not aware of a negative procedural control. II. Based on review of the manufacturer's instructions, quality control records, patient testing logs, and interview, the laboratory failed to document the results of the internal procedural controls for the Consult Diagnostics Strep A Tests Dipstick for 10 of 10 patients tested from 03/04/2023 - 03/19/2023. Findings follow. A. Review of the McKesson Consult Diagnostics Strep A Tests Dipstick, PVN C0218, under Internal Quality Control stated, "Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result." B. Review of the Laboratory Master Specimen Log from 03/04/2023 - 03/19/2023 showed the documentation of the QC and patient testing logs: and showed 4 out of 10 missing the results of the positive procedural control, and 6 out of 10 missing the results for the negative procedural control: Date of Service Account # Missing Procedural Control 1. 03/19/2023 22691 Neg 2. 03/13/2023 22551 Neg 3. 03/10/2023 22486 Neg 4. 03/08/2023 22422 Neg 5. 03/07/2023 22406 Neg 6. 03/06/2023 22378 Pos 7. 03/07/2023 22381 Pos 8. 03/06/2023 22374 Neg 9. 03/05/2023 22348 Pos 10. 03/06/2023 22353 Pos C. Interview with Technical Consultant #2, as listed on the CMS Form 209, on May 11, 2023 at 1835 hours in the laboratory acknowledged they should be documenting the internal controls. Interview with testing personnel #8 on May 11, 2023 at 1900 hours in the break room acknowledged he was not aware of a negative procedural control. III. Based on review of the manufacturer's instructions, quality control records, patient testing logs, and interview, the laboratory failed to document the results of the internal procedural controls for the Consult Diagnostics Mononucleosis Tests Cassette for 1 of 1 patients tested from 03/04/2023 - 03/19/2023. Findings follow. A. Review of the McKesson Consult Diagnostics Mononucleosis Tests Cassette, Rev.00 12/15 P-52021-B, under Quality Control stated, "There are two internal control features in McKesson Consult Mononucleosis Cassette Test. A colored control band will always appear at the Control position (C) if the test has been performed correctly and if the device is working properly. This is considered an internal positive procedural control. A clear background in the result window is considered an internal negative procedural control. If the test has been performed correctly and McKesson Consult Mononucleosis Cassette Test is working properly, the background in the result window will be clear, providing a distinct result." B. Review of the Laboratory Master Specimen Log from 03/04/2023 - 03/19/2023 showed the documentation of the QC and patient testing logs: and showed 1 out of 1 missing the results of the negative procedural control: Date of Service Account # Missing Procedural Control 1. 03/19/2023 22691 Neg C. Interview with Technical Consultant #2, as listed on the CMS Form 209, on May 11, 2023 at 1835 hours in the laboratory acknowledged they should be documenting the internal controls. Interview with testing personnel #8 on May 11, 2023 at 1900 hours in the break room acknowledged he was not aware of a negative procedural control.

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 quality control (QC) records, installation records, interview, and pre-survey paperwork, the laboratory failed to monitor over time the accuracy and precision of the Complete Blood Count (CBC) performed on the Sysmex XP-300 for 17 of 18 months reviewed. Findings follow. A. Review of QC records showed no monthly QC reports for the CBC which included calculations for mean and standard deviation (SD), along with QC target ranges prior to 03/30/2023. B. Review of the installation records showed the analyzer was installed on 11/04/2021. C. Interview with Technical Consultant #2, as listed on the CMS Form 209, on May 11, 2023 at 1535 hours in the laboratory confirmed the lab did not print QC reports showing daily QC performance, Levy Jennings, calculations for mean and SD, and the target ranges. D. Review of the CMS Form 116 showed an estimated 12,000 measured indices reported annually.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(v)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of the proficiency testing records, competency evaluation forms, and interview, the technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for 5 out of 11 testing personnel competencies reviewed for the Complete Blood Counts (CBC) on the Sysmex XP-300, Troponin and D-Dimer using the Triage Alere, and Metlac 12 on the Piccolo Xpress. Findings follow. A. Review of the American Proficiency Institute (API) proficiency testing records attestation statements from the 1st event of 2023, and the 1st, 2nd, and 3rd events from 2022 showed testing personnel #1, 2, 5, 6, and 11, as listed on the CMS form 209, did not participate in proficiency testing. B. Review of the competency evaluations from 2022 stated, "Performs Proficiency Testing" with n/a or a line marked through for testing personnel # 2, 5, 6, and 11 for the CBC, Troponin, D-Dimer, and the Metlac 12. C. Interview with Technical Consultant #2, as listed on the CMS Form 209, on May 11, 2023 at 1450 hours in the break room confirmed test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing was not done for the PRNs.