

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0482521	<b>(X3) Date Survey Completed</b>  04/06/2022
<b>Name of Provider or Supplier</b>  East Texas Clinic Association	<b>Street Address, City, State</b>  101 Willis Ave, Naples, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. .
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy, API agency policy, API proficiency test results from 2020-2021 and confirmed in an interview found the laboratory failed to verify one of six PT events per the API agency policy for accuracy of one of one ungraded analyte: urine sediment in 2020 Hematology/Coagulation-3rd event. The findings were: 1. Review of the laboratory's policy titled Policy for Evaluation of Proficiency Testing Performance, "The laboratory director, along with the testing personnel, will review and evaluate all of the proficiency testing scores when results are received and check the accuracy of all tests, including a zero for a late submission, or a 100% score for an ungraded challenge." 2. Review API Proficiency Testing Performance Evaluation page revealed "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes." 3. Review of the laboratory's API Hematology/Coagulation proficiency testing records from 2020 to 2021 revealed the laboratory had no documentation of review of the analyte with a grade of "not graded" for one of six PT events: 2020 Hematology/Coagulation-3rd event. 2020 Hematology/Coagulation-3rd event</p>

Microscopy/Urine Sediment Analyte/Method urine sediment Sample: US-06 Reported Result: Cast (granular) Expected Result: See Data Summary 4. An interview with RN on 4/6/22 at 11:00 am in the office confirmed the above findings. Key: API= American Proficiency Institute PT=Proficiency testing RN=Registered Nurse

**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 the review of the laboratory's API proficiency test results from 2020-2021 and confirmed in an interview found the laboratory failed to verify the accuracy of the analyte vaginal wet preparation at least twice annually in 2020. The findings were: 1. Review of the laboratory's API Hematology/Coagulation proficiency testing records from 2020 to 2021 revealed unacceptable performance score of 0% for the analyte Vaginal Wet Preparation in Microscopy/Urine Sediment for two of six PT events in 2020 Hematology/Coagulation-1st event and 2020 Hematology/Coagulation-3rd event. 2. Further review of the laboratory's API Hematology/Coagulation proficiency testing records for 2020 Hematology/Coagulation-1st event and 2020 Hematology/Coagulation-3rd event revealed unacceptable performance score of 0% for the analyte Vaginal Wet Preparation in Microscopy/Urine Sediment for two of six PT events. The unacceptable performance were: 2020 Hematology/Coagulation-1st event Microscopy/Urine Sediment Vaginal Wet Preparation 0% Sample:VA-01 Reported Result: Clue cells seen Expected Result: No yeast, Trich, or clue cells 2020 Hematology/Coagulation-3rd event Microscopy/Urine Sediment Vaginal Wet Preparation 0% Sample:VA-03 Reported Result: Clue cells seen Expected Result: No yeast, Trich, or clue cells 3. An interview with RN on 4/6/22 at 11:00 am in the office confirmed the above findings. Key: API= American Proficiency Institute PT=Proficiency testing RN=Registered Nurse

**D5461**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's direct observation, the laboratory reagent replacement history logs from 12/6/21 to 3/29/22, and confirmed in an interview found the laboratory failed to document a quality control run after a change in a reagent on one of one Sysmex XN-330 hematology analyzer for two of 10 days reviewed. The findings were: 1. The surveyor's direct observation in the laboratory revealed four reagents were used for the XN-330 hematology analyzer (SN#:11446) Cellpack DCL Sulfolyser Lysercell WDF Fluorocell WDF 2. Review of the reagent replacement history logs from 12/6/21 to 3/29/22 revealed two of 10 days reviewed with no

documentation of the quality control run after the following reagent change on the Sysmex XN-330 (SN#11446) hematology analyzer. 3/4/22 at 9:02 am Cellpack DCL Lot#Y1031 Exp 5/16/2023 3/29/22 at 10:22 am Cellpack DCL Lot#Y1033 Exp 6/26 /2023 3. Review of the patient test records for the above date revealed the laboratory performed two patient testing after the reagent change above with no documentation of the quality control run. 3/4/22 at 11:21 am Patient ID: 23883 3/29/22 at 12:00 pm Patient ID:29115 4. An interview with RN on 4/6/22 at 11:30 am in the office confirmed the above findings. Key: RN=Registered Nurse

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:  
Based on the review of the laboratory's policy, API proficiency test results from 2020-2021 and confirmed in an interview found the LD failed to document the evaluation and verification for one of six PT events in 2020 Hematology/Coagulation-3rd event. The findings were: 1. Review of the laboratory's policy titled Policy for Evaluation of Proficiency Testing Performance, "The laboratory director, along with the testing personnel, will review and evaluate all of the proficiency testing scores when results are received and check the accuracy of all tests, including a zero for a late submission, or a 100% score for an upgraded challenge....Verification of these results will be documented.... The director will then sign and date the data logsheet to verify that results have been evaluated." 2. Review of the laboratory's API Hematology /Coagulation proficiency testing records from 2020 to 2021 revealed no documentation of evaluation and verification by the LD for one of six PT events. 2020 Hematology/Coagulation-3rd event 3. Review of the API proficiency test results for the 2020 Hematology/Coagulation-3rd event revealed five of five proficiency samples received unacceptable performance for the analyte Lymphocytes(%) of Blood Cell Differential resulting in a score of 0%. Lymphocytes (%) Sample:XE-11 Reported Result: 2.2 Expected Result: 26.4-30.9 Sample:XE-12 Reported Result: 0.9 Expected Result: 29.7-37.0 Sample:XE-13 Reported Result: 1.8 Expected Result: 26.3-31.0 Sample:XE-14 Reported Result: 4.9 Expected Result: 26.6-30.6 Sample:XE-15 Reported Result: 0.7 Expected Result: 25.8-31.9 4. Further review of the API proficiency test results for the 2020 Hematology/Coagulation-3rd event revealed unacceptable performance score of 0% for the analyte Vaginal Wet Preparation in Microscopy/Urine Sediment. The unacceptable performance was: 2020 Hematology /Coagulation-3rd event Microscopy/Urine Sediment Vaginal Wet Preparation 0% Sample:VA-03 Reported Result: Clue cells seen Expected Result: No yeast, Trich, or clue cells 5. An interview with RN on 4/6/22 at 11:00 am in the office confirmed the above findings. Key: API= American Proficiency Institute LD=Laboratory Director PT=Proficiency testing RN=Registered Nurse

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy, API proficiency test results from 2020-2021 and confirmed in an interview found the LD failed to document corrective action for unacceptable performance PT results for one of six PT events. The findings were:

1. Review of the laboratory's policy titled Policy for Evaluation of Proficiency Testing Performance, "The laboratory director, along with the testing personnel, will review and evaluate all of the proficiency testing scores when results are received and check the accuracy of all tests, including a zero for a late submission, or a 100% score for an upgraded challenge. Verification of these results will be documented.... The director will then sign and date the data logsheet to verify that results have been evaluated."
2. Review of the laboratory's API Hematology/Coagulation proficiency testing records from 2020 to 2021 revealed unacceptable performance score of 0% for the analyte Lymphocytes(%) in White Blood Cell Differential for one of six PT events. The unacceptable performance were: 2020 Hematology/Coagulation-3rd event White Blood Cell Differential Lymphocytes(%) 0%
3. Review of the laboratory's API 2020 Hematology/Coagulation-3rd event revealed no documentation of corrective action and signed by the LD.
4. An interview with RN on 4/6/22 at 11:00 am in the office confirmed the above findings.

Key: API= American Proficiency Institute  
LD=Laboratory Director PT=Proficiency testing RN=Registered Nurse