

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0487467	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Nocona General Hospital	Street Address, City, State 100 Park Rd, Nocona, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, patient records, and confirmed in interview, the laboratory failed to document the Wright Gemsa (hematology differentials) stain adequacy (reactivity/stain quality) for patient slides. Findings were as follows: a. At the time of of the survey January 21, 2020 the surveyor asked for documentation for the quality control for the Wright Gemsa stain used for Blood manual differentials. The laboratory failed to produce any documentation. b. During an interview on 01/21 /20 at 10:20 AM, the General Supervisor confirmed the stain adequacy for Wright Gemsa was not documented ..</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p>

This STANDARD is not met as evidenced by:
Based on a review of quality control records for the corrective action policy and confirmed in interview, the laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability. Findings were as follows: a .At the time of the survey the laboratory failed to provide a Quality Control policy to include patients prior to quality control failures back to the last successful quality control run were evaluated to ensure the accuracy of the patient results reported. b. An interview of the General Supervisor on 01/21/2020 at 11:00 hours in the laboratory confirmed the above findings.

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 quality assessment reports and interview, the laboratory failed to establish a written policy for ongoing mechanism to monitor, assess and correct problems identified in analytical systems. Findings were: a. At the time of the survey the laboratory failed to provide a Quality assessment policy documentation for Quality Control and problems in the analytical systems, for the chemistry analyzer Vitros problem for October 2019 (Bad QC, Bad Cal) for analytes Sodium, Total Protein, Alk Phos, Albumin, Bu, Bc, Cholesterol Chloride, Total Bilirubin, for 10/12 /2019 and 1/25/2019 , 10/11/2019 18 patients tested 10/12/2019 10 patient tested, b An interview with the general supervisor on 01/22/2020 at 11:00 hrs in the conference room confirmed the above findings