

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0303966	(X3) Date Survey Completed 03/27/2024
Name of Provider or Supplier Bullock County Hospital	Street Address, City, State 102 Conecuh Avenue, Union Springs, AL	
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 following deficiencies are a result of a desk review of proficiency testing scores obtained from the national database and verified in an interview with the Laboratory Manager on 3/27/2024. The laboratory was found to be out of compliance with CONDITION LEVEL DEFICIENCIES , as follows: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director .
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CASPER Reports 0153D and 155D, and a telephone interview with the Laboratory Manager, the surveyor determined the laboratory failed</p>

to successfully participate in proficiency testing for the Subspecialty of Endocrinology and the analyte TSH (Thyroid Stimulating Hormone) for two out of three testing events, 2023-Event #2 and 2024-Event #1; these failures resulted in initial unsuccessful proficiency testing performance. The findings include: 1. A review of the CASPER Reports revealed the laboratory received failing scores for two out of three testing events, resulting in initial unsuccessful proficiency testing performance, as follows: A) 2023-Event #2: TSH-20%, resulting in a failing score of 73% in the Subspecialty of Endocrinology; and B) 2024-Event #1: TSH-20%, Free Thyroxin (Free T4)-20%, and Thyroxin (T4)-40%, resulting in a failing score of 45% in the subspecialty of Endocrinology. 2. During a telephone interview on 3/27/2024 at 12:50 PM, the Laboratory Manager confirmed the above failing proficiency testing scores.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of the CASPER Report 0155D (Individual Laboratory Profile) and an interview with the Laboratory Manager, the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three testing events for Endocrinology, a Subspecialty of the Specialty of Chemistry. The findings included: 1. A review of the CASPER Report 0155D report revealed the following API (American Proficiency Institute) proficiency testing score failures in the subspecialty of Endocrinology: A) 2023-Event #2: TSH-20%, resulting in a failing score of 73% in the Subspecialty of Endocrinology B) 2024-Event #1: TSH-20%, Free Thyroxin (Free T4)-20%, and Thyroxin (T4)-40%, resulting in a failing score of 45% in the Subspecialty of Endocrinology. 2. During a telephone interview on 3/27/2024 at 12:50 PM, the Laboratory Manager confirmed the above failing proficiency testing scores.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on a proficiency testing desk review of the CASPER Report 0155D (Individual Laboratory Profile) and an interview with the Laboratory Manager, the laboratory failed to achieve satisfactory performance (80% or greater) for two out of three testing events for TSH (Thyroid Stimulating Hormone). The findings included: 1. A review of the CASPER Report 0155D revealed the following API (American Proficiency Institute) proficiency testing scores: A) Chemistry 2023-Event #2: TSH with a failing score of 20% B) Chemistry 2024-Event #1: TSH with a failing score of 20% 2. During a telephone interview on 3/27/2024 at 12:50 PM, the Laboratory Manager confirmed the above failing proficiency testing scores. .

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a proficiency testing desk review of the CASPER Report 0155D (Individual Laboratory Profile) and an interview with the Laboratory Manager on 3/27/2024, the Laboratory Director failed to provide overall management and direction of the laboratory services. (Refer to D6016.)

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a proficiency testing desk review of the CASPER Report 0155D (Individual Laboratory Profile) and an interview with the Laboratory Manager on 3/27/2024, the Laboratory Director failed to ensure successful participation in an HHS (Health and Human Services) approved proficiency testing program. The laboratory failed to successfully participate in proficiency testing for the subspecialty of Endocrinology and the analyte TSH (Thyroid Stimulating Hormone) for two out of three testing events, 2023-Event #2 and 2024-Event #1; these failures resulted in initial unsuccessful proficiency testing performance. (Refer to D2096 and D2107.) Surveyor ID# 32558 Licensure and Certification Surveyor