

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0305030	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Evergreen Medical Center	Street Address, City, State 101 Crestview Ave, Evergreen, 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
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 CMS CASPER reports, a review of the American Proficiency Institute (API) proficiency testing evaluations, and a telephone interview with the Laboratory Manager, the surveyor determined the laboratory failed to successfully participate in proficiency testing for Chemistry testing [Total Cholesterol, Sodium (Na) and Gentamicin] as follows: A) The laboratory scored 0 % (zero percent) for Total Cholesterol for Events #2 and #3 of 2020, two consecutive testing events. The laboratory scored 0 % for Event #3, 2020, due to a failure to submit the results for grading. B) The laboratory scored 20 % for Na for Event #1, 2020 and 0 % for Event #3, 2020, two of three consecutive testing events. C) The laboratory scored 60 % for</p>

Gentamicin for Event #1, 2020 and 0 % for Event #3, 2020, two of three consecutive testing events. These failures resulted in initial unsuccessful proficiency testing participation for the laboratory. The findings include: A review of the CASPER reports and API proficiency testing evaluations revealed the laboratory scored the above mentioned scores for Events #1, #2 and #3, 2020, resulting in unsuccessful participation for Gentamicin, Na and Total Cholesterol. During an interview on 11/17 /2020 at 10:50 AM, the Laboratory Manager confirmed the above noted findings. The Laboratory Manager stated just as she was submitting the results for Event #3, 2020, the electricity and internet failed, due to a storm/hurricane. The manager further confirmed she waited until the last day to attempt to submit the proficiency testing results to API. .

D2093

ROUTINE CHEMISTRY
CFR(s): 493.841(d)

Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on a review of CMS CASPER reports, a review of the American Proficiency Institute (API) proficiency testing evaluations, and a telephone interview with the Laboratory Manager, the surveyor determined the laboratory failed to submit the results for Event #3, 2020 to ensure grading. The failure to submit the results timely to API contributed to the laboratory's unsuccessful participation in proficiency testing for Chemistry as follows: A) The laboratory scored 0 % (zero percent) for Total Cholesterol for Events #2 and #3 of 2020, two consecutive testing events. The laboratory scored 0 % for Event #3, 2020, due to a failure to submit the results for grading. B) The laboratory scored 20 % for Na for Event #1, 2020 and 0 % for Event #3, 2020, two of three consecutive testing events. The laboratory scored 0 % for Event #3, 2020, due to a failure to submit the results for grading. C) The laboratory scored 60 % for Gentamicin for Event #1, 2020 and 0 % for Event #3, 2020, two of three consecutive testing events. The laboratory scored 0 % for Event #3, 2020, due to a failure to submit the results for grading. These failures resulted in initial unsuccessful proficiency testing participation for the laboratory. The findings include: See Also D2016.

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 review of CMS CASPER reports, a review of the American Proficiency Institute (API) proficiency testing evaluations, and a telephone interview with the Laboratory Manager, the surveyor determined the laboratory failed to satisfactorily perform in proficiency testing for Sodium (Na), Gentamicin and Total Cholesterol. The failure to submit the results timely to API for Event #3, 2020 contributed to the laboratory's unsatisfactory performance and unsuccessful participation for Chemistry

as follows: A) The laboratory scored 0 % (zero percent) for Total Cholesterol for Events #2 and #3 of 2020, two consecutive testing events. The laboratory scored 0 % for Event #3, 2020, due to a failure to submit the results for grading. B) The laboratory scored 20 % for Na for Event #1, 2020 and 0 % for Event #3, 2020, two of three consecutive testing events. The laboratory scored 0 % for Event #3, 2020, due to a failure to submit the results for grading. C) The laboratory scored 60 % for Gentamicin for Event #1, 2020 and 0 % for Event #3, 2020, two of three consecutive testing events. The laboratory scored 0 % for Event #3, 2020, due to a failure to submit the results for grading. The findings include: See Also D2016.

D6090

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on a review of CMS CASPER reports, a review of the American Proficiency Institute (API) proficiency testing evaluations, and a telephone interview with the Laboratory Manager, the surveyor determined the Laboratory Director failed to ensure results for Event #3, 2020 were submitted to the provider to ensure grading. API scored the laboratory zero percent (0 %) for Event #3, 2020, due to the laboratory's failure to submit the results. The failure to submit the results timely to API contributed to the laboratory's unsuccessful participation in proficiency testing for several analytes in Chemistry. The findings include: See Also D2016.