

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0871507	(X3) Date Survey Completed 08/15/2018
Name of Provider or Supplier Kevin G Kelly Md	Street Address, City, State 13150 Hwy 43 South Suite 10, Russellville, 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 the CASPER reports (#153/#155), a review of American Association of Bioanalysts (AAB) performance evaluations for Hematology, and telephone interviews with the laboratory personnel and an AAB representative, the surveyor determined the laboratory failed Hematocrit (HCT) for three of five testing events, Event #3, 2016; Event #2, 2017; and Event #1, 2018. These failures resulted in non-initial unsuccessful proficiency testing participation for HCT for the laboratory. Additionally, the laboratory's overall Hematology scores for Event #2, 2017 of 42 % and for Event #1, 2018 of 0 % (due to untimely submission), resulted in unsuccessful proficiency testing participation for the specialty. The findings include: 1. Cited on 8</p>

/16/17, Initial Unsuccessful Proficiency Testing Participation: a) A review of the CASPER reports and the AAB performance evaluations revealed the laboratory scored 60 % (percent) for the HCT for Event #3, 2016 and 20 % for Event #2, 2017, two of three consecutive testing events. These failures resulted in the laboratory's initial unsuccessful proficiency testing performance. b) The above noted findings were confirmed by an AAB representative on 8/16/17 at 12:00 PM, during a telephone interview. 2. A review of AAB proficiency testing evaluations on 8/14/18 revealed the laboratory scored 0 % for HCT for Event #1 of 2018, in addition to the earlier failures; thus resulting in unsuccessful participation for three of five testing events. 3. In a telephone interview on 8/15/18 at 11:05 AM, the testing personnel confirmed the laboratory failed to timely submit the data to AAB for grading for Event #1, 2018, resulting in zero percents scores for all analytes.

D2122

HEMATOLOGY
CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on a review of the CASPER reports (#153/#155), a review of American Association of Bioanalysts (AAB) performance evaluations for Hematology, and a telephone interview with the laboratory personnel, the surveyor determined the laboratory failed Hematology testing for two events, Event #2, 2017 and Event #1, 2018, two of three consecutive testing events. The findings include: 1. The laboratory's overall Hematology scores for Event #2, 2017 of 42 % and for Event #1, 2018 of 0 % (due to untimely submission), resulted in unsuccessful proficiency testing participation for the specialty. 2. By review of AAB proficiency testing evaluations on 8/14/18, the surveyor confirmed the laboratory scored 0 % for Hematology (zero percent scores for all analytes) for Event #1 of 2018, and an overall 42 % for Event #2, 2017 [53 % for the White Blood Cell Differential, 20 % for RBC (Red Blood Cell Count), Hematocrit and Hemoglobin; and 40 % for WBC (White Blood Cell Count)]. 3. In a telephone interview on 8/15/18 at 11:05 AM, the testing personnel confirmed the laboratory failed to timely submit the data to AAB for grading for Event #1, 2018, resulting in zero percents scores for all analytes.

D2123

HEMATOLOGY
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on a review of the CASPER reports (#153/#155), a review of American

Association of Bioanalysts (AAB) performance evaluations for Hematology, and a telephone interview with the laboratory personnel, the surveyor determined the laboratory failed Hematology testing for Event #1, 2018 (zero percent scores for all analytes, failure to participate), due to the laboratory's failure to timely submit the testing results to AAB for grading. The findings include: 1. A review of AAB proficiency testing evaluations on 8/14/18 revealed the laboratory scored 0 % for all analytes for Hematology testing for Event #1 of 2018. 2. In a telephone interview on 8/15/18 at 11:05 AM, the testing personnel confirmed the laboratory failed to timely submit the data to AAB for grading for Event #1, 2018, resulting in zero percent scores for all analytes (a failure to participate).

D2127

HEMATOLOGY
CFR(s): 493.851(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 the CASPER reports (#153/#155), a review of American Association of Bioanalysts (AAB) performance evaluations for Hematology, and a telephone interview with the laboratory personnel, the surveyor determined the laboratory failed Hematology testing for Event #1, 2018, due to the laboratory's failure to submit, within the established timeframe, the testing results to AAB for grading. The findings include: 1. By review of AAB proficiency testing evaluations on 8/14/18, the surveyor confirmed the laboratory scored 0 % for Hematology (zero percent scores for all analytes) for Event #1 of 2018, and an overall 42 % for Event #2, 2017 [53 % for the White Blood Cell Differential, 20 % for RBC (Red Blood Cell Count), Hematocrit and Hemoglobin; and 40 % for WBC (White Blood Cell Count)]. 2. In a telephone interview on 8/15/18 at 11:05 AM, the testing personnel confirmed the laboratory failed to timely submit the data to AAB for grading for Event #1, 2018, resulting in zero percent scores for all analytes. 3. The laboratory's overall Hematology score for Event #1, 2018 of 0 %, due to untimely submission is considered unsatisfactory performance.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for 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 the CASPER reports (#153/#155), a review of American Association of Bioanalysts (AAB) performance evaluations for Hematology, and a telephone interview with the laboratory personnel, the surveyor determined the laboratory failed Hematology testing for two events, Event #2, 2017 and Event #1, 2018, two of three consecutive testing events. The findings include: 1. The laboratory's overall Hematology scores for Event #2, 2017 of 42 % and for Event #1, 2018 of 0 % (due to untimely submission), resulted in unsuccessful proficiency testing participation for the specialty. 2. By review of AAB proficiency testing evaluations on

8/14/18, the surveyor confirmed the laboratory scored 0 % for Hematology (zero percent scores for all analytes) for Event #1 of 2018, and an overall 42 % for Event #2, 2017 [53 % for the White Blood Cell Differential, 20 % for RBC (Red Blood Cell Count), Hematocrit and Hemoglobin; and 40 % for WBC (White Blood Cell Count)]. 3. In a telephone interview on 8/15/18 at 11:05 AM, the testing personnel confirmed the laboratory failed to timely submit the data to AAB for grading for Event #1, 2018, resulting in zero percents scores for all analytes.

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 review of the CASPER reports (#153/#155), a review of American Association of Bioanalysts (AAB) performance evaluations for Hematology, and telephone interviews with the laboratory personnel and an AAB representative, the surveyor determined the laboratory director failed to ensure the laboratory successfully participated in Hematology (Hematocrit) testing for three of five testing events, Event #3, 2016; Event #2, 2017; and Event #1, 2018. These failures resulted in non-initial unsuccessful proficiency testing participation for HCT for the laboratory. Additionally, the laboratory's overall Hematology scores for Event #2, 2017 of 42 % and for Event #1, 2018 of 0 % (due to untimely submission), resulted in unsuccessful proficiency testing participation for the specialty. The findings include: 1. Cited on 8/16/17, Initial Unsuccessful Proficiency Testing Participation: a) A review of the CASPER reports and the AAB performance evaluations revealed the laboratory scored 60 % (percent) for the HCT for Event #3, 2016 and 20 % for Event #2, 2017, two of three consecutive testing events. These failures resulted in the laboratory's initial unsuccessful proficiency testing performance. b) The above noted findings were confirmed by an AAB representative on 8/16/17 at 12:00 PM, during a telephone interview. 2. A review of AAB proficiency testing evaluations on 8/14/18 revealed the laboratory scored 0 % for HCT for Event #1 of 2018, in addition to the earlier failures; thus resulting in unsuccessful participation for three of five testing events. 3. In a telephone interview on 8/15/18 at 11:05 AM, the testing personnel confirmed the laboratory failed to timely submit the data to AAB for grading for Event #1, 2018, resulting in zero percents scores for all analytes.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

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)(ii) Ensure that 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 the CASPER reports (#153/#155), a review of American

Association of Bioanalysts (AAB) performance evaluations for Hematology, and a telephone interview with the laboratory personnel, the surveyor determined the laboratory director failed to ensure the laboratory submitted proficiency testing results of Hematology testing, Event #1, 2018, to the provider within the established timeframe for grading. This failure to submit the results within the established timeframe resulted in a failure to participate (zero percent scores). The findings include: 1. Refer to D2127. Patricia Watson, BS, MT (ASCP) Licensure and Certification Supervisor