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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 36D0876167 | (X3) Date Survey Completed 01/17/2019 |
| Name of Provider or Supplier Parkview Bryan Hospital Laboratory | Street Address, City, State 433 West High Street, Bryan, OH | |
| 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 |
|---------------------------|--|
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with Technical Supervisor (TS) #1, TS#3, and TS#4, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Consultants (TC) for the moderately complex testing procedures performed and the Technical Supervisors (TS) and General Supervisors (GS) for the highly complex testing procedures performed based on the responsibilities of their positions. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 01/07/2019, revealed that the laboratory did not indicate at least one individual as a TC for the moderately complex blood gas and activated clotting time (ACT) testing procedures performed, however did indicate five individuals as TS's and 14 individuals as GS's. 2. Review of the laboratory's "Competency Assessment Instructions" policy and procedure, approved, signed and dated by the Laboratory Director on 03/18 and provided on the date of the inspection, did not find any mention of a competency assessment policy and procedure for the assessment of the TC's, TS's and GS's based on the responsibilities of each position. 3. The Surveyor requested the laboratory's TC, TS and GS competency assessment policies and procedures and the 2018 TC, TS and GS assessment documentation from TS#1, TS#3 and TS#4. TS#1, TS#3 and TS#4 confirmed that the laboratory did not establish and follow a competency assessment policy and procedure for the assessment of the TC, TS and GS, did not assess the TC and GS competencies based on the responsibilities of each of the positions and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 01/16/2019 at 1:15 PM.</p> |

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and interviews with Technical Supervisor (TS) #1, TS#3, TS#4 and Testing Personnel (TP) #55, the laboratory failed to have a Technical Consultant (TC) who met the qualification requirements of 493.1411 of this subpart and who provided technical oversight of the moderately complex blood gas and activated clotting time (ACT) testing procedures performed. Findings Include: 1. The laboratory failed to indicate at least one individual who met the Technical Consultant (TC) qualification requirements and who provided technical consultation for the moderately complex blood gas testing procedures performed. (Refer to D6034, Item 1) 2. The laboratory failed to indicate at least one individual who met the Technical Consultant (TC) qualification requirements and who provided technical consultation for the moderately complex activated clotting time (ACT) testing procedures performed. (Refer to D6034, Item 2)

D6034

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Item 1: Based on record review and interviews with Technical Supervisor (TS) #1, TS#3, TS#4 and Testing Personnel (TP) #55, the laboratory failed to indicate at least one individual who met the Technical Consultant (TC) qualification requirements and who provided technical consultation for the moderately complex blood gas testing procedures performed. Findings Include: 1. Review of the laboratory's "Competency Assessment Instructions" policy and procedure, approved, signed and dated by the Laboratory Director on 03/18 and provided on the date of the inspection, found the following statement as defined by CLIA for high complexity test systems: "6. All documented observations...must be performed by a Tech with a minimum of two years experience. A tech with two years of experience meets CLIA defined requirements for a General Supervisor and is designated to perform competency assessments..." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 01/07/2019, found 21 individuals listed and credentialed by the Laboratory Director to perform moderately complex blood gas testing procedures, but did not find a TC listed and credentialed by the Laboratory Director for the moderately complex blood gas testing procedures performed. 3. Review of the laboratory's education records and the 2017 and 2018 blood gas competency assessment documentation provided on the date of the inspection, revealed individuals that did not meet the minimum TC qualification requirements,

were listed and credentialed on the CMS-209 by the Laboratory Director as TP only and were indicated, by initials/signature as conducting the blood gas competency assessments as follows: TP20 (HS) 2017 assessed TP48 TP36 (HS) 2017 assessed TP49 TP37 (AAS-RC) 2017 assessed TP42, TP48, TP49 2018 assessed TP42, TP48, TP49, TP51, TP53, TP54, TP56 TP39 (HS) 2018 assessed TP53 TP40 (HS) 2017 assessed TP42 2018 assessed TP42 TP41 (HS) 2017 assessed TP48 2018 assessed TP42, TP48, TP51 TP42 (HS) 2017 assessed TP48 TP44 (HS) 2018 assessed TP48 TP46 (AAS-RC) 2018 assessed TP53, TP54 TP49 (AAS-RC) 2017 assessed TP42, TP49, TP54 2018 assessed TP49, TP53 TP55 (AAS-RC) 2017 assessed TP42, TP48, TP49, TP54 2018 assessed TP42, TP48, TP49, TP51, TP53, TP54 HS; high school diploma AAS-RC; Associates in Applied Science in Respiratory Care Degree 4. TS#1, TS#3, TS#4 and TP#55 stated the laboratory utilized inconsistent guidance received from another accrediting organization and upon review of the CLIA regulations confirmed the above mentioned TP had assessed the competency of blood gas TP as listed above and that the highest level of education that TP20, TP36, TP37, TP39, TP40, TP41, TP42, TP44, TP46, TP49 and TP55 had achieved did not meet the minimum CLIA TC qualification requirements. The interviews occurred as education documentation was provided throughout the days of the inspection on 01/15/2019, 01/16/2019 and 01/17/2019. Item 2: Based on record review and interviews with Technical Supervisor (TS) #1, TS#3, and TS#4, the laboratory failed to indicate at least one individual who met the Technical Consultant (TC) qualification requirements and who provided technical consultation for the moderately complex activated clotting time (ACT) testing procedures performed. Findings Include: 1. Review of the laboratory's "Competency Assessment Instructions" policy and procedure, approved, signed and dated by the Laboratory Director on 03/18 and provided on the date of the inspection, found the following statement as defined by CLIA for high complexity test systems: "6. All documented observations...must be performed by a Tech with a minimum of two years experience. A tech with two years of experience meets CLIA defined requirements for a General Supervisor and is designated to perform competency assessments..." 2. Review of the laboratory's Form CMS-209, approved, signed, and dated by the Laboratory Director on 01/07/2019, found 10 individuals listed and credentialed by the Laboratory Director to perform moderately complex ACT testing procedures, but did not find a TC listed and credentialed by the Laboratory Director for the moderately complex ACT testing procedures performed. 3. Review of the laboratory's education records and the 2018 "Cath Lab Competency Evaluation" documentation provided on the date of the inspection, revealed individuals that did not meet the minimum TC qualification requirements, were listed and credentialed on the CMS-209 by the Laboratory Director as TP only and were indicated, by initials/signature as conducting the ACT competency assessments as follows: TP27 (HS) 2018 assessed TP29, TP30, TP32, TP57 TP33 (HS) 2018 assessed TP28, TP31, TP34 TP34 (HS) 2018 assessed TP27, TP33 4. TS#1, TS#3 and TS#4 stated the laboratory utilized inconsistent guidance received from another accrediting organization and upon review of the CLIA regulations confirmed the above mentioned TP had assessed the competency of ACT TP as listed above and that the highest level of education that TP27, TP33 and TP34 had achieved did not meet the CLIA minimum TC qualification requirements. The interviews occurred as education documentation was provided throughout the days of the inspection on 01/15/2019, 01/16/2019 and 01/17/2019.