

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0991572	<b>(X3) Date Survey Completed</b> 06/05/2019
<b>Name of Provider or Supplier</b> Good Shepherd Rehabilitation Hospital	<b>Street Address, City, State</b> 3200 Center Valley Parkway, Center Valley, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 review of Laboratory procedure manuals and interview with the director of respiratory therapy, the laboratory failed to establish a complete competency assessment procedure to assess (11 of 11) testing personnel (TP) who performed blood gases test and clinical consultant competency (2 of 3) from 09/21/2017 to the date of survey. Findings Include: 1. On the day of survey, 06/05/2019, the laboratory failed to provide a complete written policy on how to assess the competency of 11 of 11 TP who performed blood gases tests and 2 of 2 Clinical consultant's competency in 2017 and 2018. 2. The director of respiratory therapy confirmed the finding above on 06/05/2019 around 11:00 am.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of blood gases policies and interview with the director of respiratory therapy the laboratory failed to establish a quality assurance policy 09/21/2017 to the</p>

date of survey. Findings Include: 1. On the day of survey, 06/05/2019, the laboratory could not provide a policy for monitoring its pre-analytical, analytical, and post analytic programs from 09/21/2017 to 06/05/2019. 2. The director of respiratory therapy confirmed the findings above on 06/05/2019 around 10:30 am.

**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 review of the CLIA ' s laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the Director of respiratory therapy the laboratory failed to ensure 1 of 2 technical consultants meet the qualifications under C.F.R. 493.1411 for blood gases testing performed on the Instrumentation Labortaory GEM 400 analyzer for 2017 to the date of survey. See D6035.

**D6035**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be

qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on review of the CLIA ' s laboratory Personnel Report (Form CMS-209), review of Personnel Qualification records, and interview with the director of respiratory therapy the laboratory failed to ensure 1 of 2 technical consultants meet the qualifications under C.F.R. 493.1411 for blood gases testing performed on the Instrumentation Labortaory GEM 400 analyzer for 2017 to the date of survey. Findings Include: 1. Form CMS -209 signed by the laboratory director on 05/17/2019, lists laboratory personnel (LP) #2 as a technical consultant. 2. On the day of survey, 06/05/2019, review of educational records, revealed LP #2's diploma was printed in Latin. The laboratory was given until 06/12/2019 to send a transcript written in English. 3. Review of the transcript sent on 06/07/2019, revealed LP #2 graduated from Mulenburg College with a Major in Business Administration. Accordingly, LP #2 does not meet the educational qualifications under C.F.R. 493.1411. 4. The Director of respiratory therapy was contacted by email on Monday, June 10th, 2019 at 8:46 am to confirm the findings above.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) competency records and interview with the director of respiratory therapy, the laboratory technical consultant failed to evaluate and document the competency assessment for 10 of 11 TP in 2018. Findings include: 1. On the day of survey, 06/05/2019, the laboratory could not provide documentation for the 2018 competency performed on 10 of 11 TP. 2. The director of respiratory therapy confirmed the finding above on 06/05/2019 around 11:00 am.