

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0435278	(X3) Date Survey Completed 08/06/2025
Name of Provider or Supplier Hshs Good Shepherd Hospital Laboratory	Street Address, City, State 200 S Cedar St, Shelbyville, IL	
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 review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, lack of documentation, and interview with the laboratory representative; the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one technical consultant (TC)/technical supervisor (TS)/general supervisor (GS). Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed one TC performing moderate complexity duties for the specialties of chemistry and hematology. This same individual served as the TS and GS performing high complexity duties for the specialty of immunohematology. 2. Review of laboratory policies and procedures revealed the laboratory lacked a competency assessment policy and procedure to assess the competency of one of one TC/TS/GS. 3. Interview with the laboratory representative on 08/05/2025, at 1:31 pm, confirmed the laboratory failed to have a competency assessment policy and procedure in place to assess employee competency for one of one TC, TS, and GS.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p>

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, laboratory records, Individualized Quality Control Plans (IQCPs), lack of documentation, and interview with the laboratory representative; the laboratory failed to have 31 of 31 standard operating procedures (SOPs) and two of two IQCPs reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Report) for the specialties of chemistry, hematology, and immunochemistry. Findings include: 1. Review of laboratory policy and procedure manuals revealed no laboratory director (LD) approval, including signature and date, by the current LD for the following 31 of 31 SOPs reviewed: i. Acetaminophen ii. Alanine aminotransferase iii. Albumin iv. Alkaline phosphatase v. Ammonia vi. Amylase vii. Aspartate aminotransferase viii. Bilirubin, total ix. Bilirubin, direct x. Blood Gas/Oximetry xi. Blood Urea Nitrogen xii. Calcium xiii. Carbon dioxide xiv. Coagulation xv. Creatinine xvi. Creatinine kinase xvii. Electrolytes xviii. Ethyl Alcohol xix. Glucose xx. Immunochemistry xxi. Hematology xxii. Lactic acid xxiii. Lipase xxiv. Magnesium xxv. Phosphorus xxvi. Pro-BNP [B-type natriuretic peptide] xxvii. Protein, total xxviii. Salicylate xxix. Toxicology xxx. Troponin xxxi. Vancomycin 2. Review of laboratory records revealed no LD approval, including signature and date, by the current LD for the following two of two IQCPs reviewed: i. Drugs of Abuse Screen ii. HCG (human chorionic gonadotropin) 3. Interview with the laboratory representative on 08/06/2025, at 10:05 am, confirmed the laboratory failed to have 31 of 31 SOPs and two of two IQCPs reviewed, approved, signed, and dated by the current LD for the specialties of chemistry, hematology, and immunochemistry.

D5445

CONTROL PROCEDURES
 CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, Individualized Quality Control Plans (IQCPs), direct observation, and interview with the laboratory representative; the laboratory failed to have the current test methodology listed for two of two IQCPs utilized for hCG (human chorionic gonadotropin) serum testing in the subspecialty of endocrinology and Drugs of Abuse (DoA) screening in the subspecialty of toxicology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Developing and Implementing an Individualized Quality Control Plan", which stated, under "Purpose:": a) "The objective of the quality control (QC) process is to outline guidelines to determine how QC is performed for tests systems in the laboratory."; and b) "The laboratory director retains overall responsibility for ensuring that QC programs are established and maintained" 2. Review of laboratory IQCPs revealed the following test methodologies documented: Test: Test Methodology: hCG serum "Sure-Vue HCG Serum" DoA screen "Alere Triage Drugs

of Abuse Panel" 3. Direct observation upon a tour of the laboratory on 08/05/2025, at 1:40 pm, revealed the following test methodologies currently being utilized: Test: Test Methodology: hCG serum Cardinal Health DoA screen Profile-V / MedToxScan (Serial Number: 1920M1062 4. Interview with the laboratory representative on 08/06/2025, at 3:05 pm, confirmed the laboratory failed to have the current test methodology listed for two of two IQCPs utilized for hCG serum testing in the subspecialty of endocrinology and DoA screening in the subspecialty of toxicology.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the CMS-209 (Laboratory Personnel Report), laboratory policies and procedures, employee competency records, lack of documentation, and interview with the laboratory representative; the technical consultant (TC) failed to evaluate and document the performance of two of six new testing personnel (TP) at least semiannually during the first year the TP tested patient specimens in the specialties of chemistry and hematology from their Date of Hire (DoH) through the date of survey, 08/06/2025. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed six new TP (TP #2, TP #4, TP #5, TP #6, TP #8, and TP #9). 2. Review of laboratory policies and procedures revealed the procedure titled "Competency Assessment & Training Activities", which stated, under "Narrative:", "Frequency for assessing competency will be done initially at hire, six months from hire, and yearly." 2. Review of employee competency records revealed two of six new TP failed to have their competency evaluated and documented at least semiannually during the first year the TP tested patient specimens. DoH: 6-month: 1st Annual: TP #6 01/02/2024 09/20/2024 Not documented TP #8 05/17/2024 01/20/2025 Not documented 3. Interview with the laboratory representative on 08/06/2025, at 3:05 pm, confirmed the TC failed to evaluate and document the performance of two of six new TP at least semiannually during the first year the TP tested patient specimens in the specialties of chemistry and hematology from their DoH through the date of survey, 08/06/2025.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, Individualized Quality Control Plans (IQCPs), lack of documentation, and interview with the laboratory representative; the laboratory failed to have 31 of 31 standard operating procedures and two of two IQCPs reviewed, approved, signed, and dated by the current laboratory director (as noted on the CMS-209 Laboratory Personnel Report) for the specialties of chemistry, hematology, and immunohematology (See D5407).

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the CMS-209 (Laboratory Personnel Report), laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory director (LD) failed to specify, in writing, the responsibilities and duties, including each individual engaged in the preanalytical, analytical, and postanalytical phases of testing, for one of one technical consultant (TC)/technical supervisor (TS) /general supervisor (GS) and nine of nine testing personnel (TP) listed on the CMS-209. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) revealed one TC performing moderate complexity duties for the specialties of chemistry and hematology. This same individual served as the TS and GS performing high complexity duties for the specialty of immunohematology. 2. Review of the CMS-209 (Laboratory Personnel Report) revealed five TP (TP #1-5) performing high complexity testing for the specialty on immunohematology and moderate complexity for the specialties of chemistry and hematology. 3. Review of the CMS-209 (Laboratory Personnel Report) revealed four TP (TP #6-9) performing only moderate complexity testing for the specialties of chemistry and hematology. 4. Review of laboratory records failed to identify documentation that specified, in writing, the responsibilities and duties, including each individual engaged in the preanalytical, analytical, and postanalytical phases of testing, for one of one TC/TS/GS and nine of nine TP (TP #1-9). 5. Interview with the laboratory representative on 08/05/2025, at 3:22 pm, confirmed the LD failed to specify, in writing, the responsibilities and duties, including each individual engaged in the preanalytical, analytical, and postanalytical phases of testing, for one of one TC/TS/GS and nine of nine TP listed on the CMS-209.