| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 23D0685754 | 02/01/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pontiac General Hospital | 461 W Huron, Pontiac, MI | |

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** |
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| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor, the laboratory failed to follow its policy to perform competency assessments for 4 (Clinical Consultant/Technical Supervisor, General Supervisor/Technical, Testing Personnel #4, and Testing Personnel #6) of 8 personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Employee Training and Competency Evaluation" policy revealed a section stating, "The competency checklist is a detailed explanation of what is on the competency calendar. The competency checklist should be completed initially, 6 months after completed training and annually thereafter. This should be checked off when the employee is proven to be competent in all areas of testing. This and the calendar should be a final step of training or competency." 2. A review of the laboratory's personnel records revealed the following personnel with a lack of competency assessment documentation: a. Clinical Consultant/Technical Supervisor had a lack of documentation of competency assessments. b. General Supervisor/Technical Supervisor had not had a competency assessment performed since 6/17/19. c. Testing Personnel #4 started testing in February 2022 and did not have documentation of initial competency assessments for the Stago Compact coagulation testing, urinalysis testing, and its C. difficile testing. d. Testing Personnel #6 had started testing in November 2021 and had no documented competency assessments available. 3. An interview on 2/1/23 at 11:09 am with the General Supervisor confirmed competency assessment had not been documented according to the laboratory's policy for the personnel listed above. |
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| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation and interview with Testing Personnel (TP) #2 and #7, the laboratory failed to ensure the reagent bottle used for immunohematology testing was labeled to indicate the identity, concentration, pour date, and expiration date of the reagent for 1 (unlabeled bottle) of 1 reagent bottles observed in innumohematology. Findings include: 1. During a tour of the immunohematology department on 2/01 /2023 at 1:21 pm, the surveyor observed a reagent bottle unlabeled in the testing area with no identity, concentration, pour date, and expiration date for the reagent. 2. When queried on 2/01/2023 TP#2 stated the reagent was for the immunohematology testing and TP#7 confirmed. 3. An interview on 2/01/2023 at 2:37 pm, TP#7 confirmed the reagent bottle in the immunohematology testing area was unlabeled and did not have all required elements recorded on the reagent label. ***Repeat Deficiency from 12/13 /2016 survey*** |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation and interview with the General Supervisor, the laboratory failed to ensure its BacT Alert blood culture media bottles had not exceeded their expiration date for 2 of 12 bottles observed. Findings include: 1. The surveyor observed two BacT Alert FN blood culture bottles with the expiration date of 1/27/23. 2. An interview on 2/1/23 at 2:39 pm with the General Supervisor confirmed the above blood culture bottles had been expired. **This is a repeat deficiency from the 7 /27/21 recertification survey** |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, record review, and interview with the Technical Supervisor (TS), the laboratory failed to perform and document pipette calibration for the Stago multi-channel pipette used for coagulation testing for 18 (August 2021 to January |

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| | 2023) of 18 months in use. Findings include: 1. During a tour of the Hematology department on 2/01/2023 at 9:20 am the surveyor observed the multi-channel Stago pipette used with the STart 4 not have a calibration sticker. 2. A record review of the pipette calibrations revealed a lack of documentation for the Stago multi-channel pipette for 18 (August 2021 to January 2023) of 18 months. 3. An interview on 2/01 /2023 at 2:25 pm, the TS confirmed the laboratory failed to include the Stago multi-channel pipette with the other pipettes when calibrated. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor, the laboratory failed to ensure results of Lithium and Creatine Kinase (CK) control materials met the laboratory's and the manufacturer's test system criteria for acceptability before reporting patient test results for 1 (1/31/23) of 5 testing dates reviewed. Findings include: 1. A review of the laboratory's "Dimension EXL 200" procedure revealed a section titled "Quality Control" stating, The Dimension requires two levels of un-assayed controls from Bio-Rad to monitor the performance for most of the general chemistries on the test menu. In addition, two levels of Ethanol/Ammonia controls, two levels of immunoassay controls, two levels of specialty controls, two levels of cardiac controls and two levels of anemia controls for more specialized tests such as Ammonia, Blood Alcohol, Vitamin B 12, Thyroids, Troponin and Glycohemoglobin. QC is performed once in a 24-hour period at a minimum. The lab may opt to run QC more frequently should they feel it's necessary" and "Review the results, record results on QC sheets repeat failed QC. Troubleshoot and if necessary, recalibrate any test out of range as required." 2. A review of the laboratory's quality control records for its Dimension EXL 200 chemistry testing revealed Lithium and CK analyte quality control testing was out of range on 1/31/23. 3. A review of the laboratory's patient testing records revealed two patients had Lithium and CK testing performed on 1/31 /23. 4. An interview on 2/1/23 at 1:43 pm with the General Supervisor confirmed patients had testing performed and reported on 1/31/23 when Lithium and CK control testing was out of range. |
| **D6092** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(iv)<br><br>The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.<br><br>This STANDARD is not met as evidenced by:<br>. Based on record review and interview with the General Supervisor, the Laboratory Director failed to follow a corrective action plan when proficiency testing results are unacceptable for 3 (2022 1st and 2nd event hematology and 2022 3rd event chemistry) of 7 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's "Proficiency Testing" policy revealed a section stating, "In the event that a Proficiency survey score does not agree with laboratory testing performance, |

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| | the following actions will be taken by the Lab Manager: a. For results in which the proficiency testing body could not reach a consensus and no grade was assigned, the lab will perform self-grading to verify the accuracy of the analyte. b. For results in which the Laboratory received a failing score for a survey, a corrective action will be created to address the unacceptable result. c. If the laboratory has more than two failing performance review scores with no evidence to support what caused the scores, testing may be suspended on the instrument at the discretion of the Lab Director until the issue is resolved." 2. A review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the following proficiency testing events with unacceptable results: a. 2022 1st event hematology i. Blood cell identification image BCI-05 received a result of unacceptable b. 2022 2nd event hematology i. White blood cell count specimen DXH-06 received a result of unacceptable c. 2022 3rd event chemistry i. Cholesterol specimen CH-15 received a result of unacceptable ii. D-dimer specimen CM-11 received a result of unacceptable iii. pH blood gas specimen BG-15 received a result of unacceptable iv. Magnesium specimen CH-14 received a result of unacceptable v. Lithium specimen CH-11 received a result of unacceptable 3. An interview on 2/1/23 at 10:45 am with the General Supervisor revealed the laboratory had not been performing corrective action for proficiency testing events with scores of 80% or greater and corrective action for the unacceptable results listed above was not performed. |