| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 04D0939862 | 01/03/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Chi St Vincent Primary And Convenient Care - Kanis | 10301 Kanis Suite 1, Little Rock, AR | |

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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| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(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.<br><br>This CONDITION is not met as evidenced by:<br>Surveyor 35659 Based on review of 2016 and 2017 CMS Casper Reports 96D, the College of American Pathologists proficiency testing results, the College of American Pathologists "CMS Performance Summary for Analytes Regulated Under the Clinical Laboratory Improvement Amendments of 1988", and interview it was determined the laboratory failed to have successful participation in proficiency testing for the specialty of Hematology and the tests of Hematology Auto Differentials as evidenced |

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| | by: Failure to achieve satisfactory performance for the specialty of Hematology and the test of Hematology Auto Differentials in two of three testing events is unsuccessful performance, as cited at D2130. |
| **D2130** | HEMATOLOGY<br>CFR(s): 493.851(f)<br><br>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Surveyor 35659 Based on review of 2016 and 2017 CMS Casper Reports 96D, the College of American Pathologists proficiency testing results, the College of American Pathologists "CMS Performance Summary for Analytes Regulated Under the Clinical Laboratory Improvement Amendments of 1988", and interview it was determined the laboratory failed to have successful participation in proficiency testing for the analytes of Hematology Auto Differentials. Findings follow: A. Review of the Casper Report 96D revealed that proficiency testing event 3 in 2016 was scored as 0 for all hematology analytes, the laboratory did not participate in proficiency testing event 1 in 2017, the laboratory was scored as unsucessful for "Cell ID or WBC Diff" for event 3 in 2017 resulting in unsuccessful participation in two of three consecutive events. B. Review of the College of American Pathologists "CMS Performance Summary" report dated 10/26/2017 revealed that the laboratory performance interpretation was scored as "unsuccessful" for Cell ID/Flow Differential. C. Review of CAP proficiency testing records revealed that the laboratory failed to participate in event CAP FH6-C in 2016 and was scored as 0, did not participate and was not scored for event CAP FH6-A in 2017, successfully participated in CAP FH9-B in 2017, and received an unsuccessful score of 0 for Cell ID/Flow Differential in event CAP FH-9 2017 which resulted in unsuccessful participation for Cell ID/Flow Differential in two of three consecutive events. D. In an interview on 1/3/18 at approximately 1545 the technical consultant identified as number 2 on the CMS 209 form confirmed that proficiency testing was unsuccessful for Cell ID/Flow Differential in two of three consecutive events in which the laboratory participated. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Surveyor 35659 Through review of policy and procedure, observation, and interview it was determined that the laboratory failed to identify seven of seven patient listings on work lists and one of one wet prep specimen with patient's first and last names and a unique patient identifier (patient date of birth or account number). Findings follow: A. Review of policy and procedure revealed that the policy of the laboratory was to identify patients by first and last names and a unique patient identifier (account number or patient date of birth. B. During a tour of seven patient care pods where urinaysis and KOH and wet prep exams are performed on 1/3/18 at approximately |

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| | 0900 four of four patient listings on a work list with urinalysis results were identified by patient last name only were observed in pod #3, three of three patient listings on a work list with urinalysis results were identified by patient last name only were observed in pod # 5, 11 of 11 patient listings on a work list with urinalysis results were identified by patient last name only were observed in pod # 7, and one of one specimen cup with a wet prep swab in a specimen cup labeled with patient last name only was observed in pod #7. C. In a concurrent interview on 1/3/18 at approximately 0900, the testing personnel identified as number 3 on the CMS 209 report confirmed the observations above and in an interview on 1/3/18 at approximately 0930 the technical consultant identified as number 2 on the CMS 209 form confirmed that the specimens should have been identified with patient first and last names and an unique patient identifier. |
| **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>Surveyor 35659 Through observation, review of package inserts, and interview it was determined that the laboratory failed to label three of three E-Check Hematology control vials with an expiration date. Findings follow: A. During a tour of the laboratory on 1/4/18 at approximately 1600, three of three vials of E-Check Hematology control vials lot #'s 73250804, 73250805, and 73250806 were observed in a cup used for control vials in current use with no label indicating the date opened or an expiration date. B. Review of the package insert for E-Check Hematology controls revealed that the controls expired 14 days after opening and placing into use. C. In an interview on 1/3/18 at approximately 1620, the technical consultant identified as number 2 on the CMS 209 report and the testing personnel identified as number 3 on the CMS 209 report confirmed that the E-Check vials identified above were currently in use and an amended expiration date or date of opening had not been placed on the vials. |
| **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>Surveyor 35659 Through observation, and interview it was determined that the laboratory failed to ensure that approximately 75 supply/reagent items that had exceeded their expiration date were not available for use. Findings follow: A. In a tour of the laboratory on 1/3/18 at approximately 1600, four of four Alere Cholestech LDX TC:GLU reagent packets lot # C11 391795 with an expiration date of 12/31/17 were observed on the testing bench adjacent to the Cholestech instrument. B. In a tour of |

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| | the laboratory on 1/3/18 at approximately 1615, 71/71 BD Vacutainer 5.0 ml. SST blood collection tubes lot # 7002870 with an expiration date of 12/31/17 were observed in a bin in the phebotomy room. C. In an interview on 1/3/18 at approximately 1620, the technical consultant identified as number 2 on the CMS 209 form and testing personnel identified as number 3 on the CMS 209 form confirmed that the items identified above had exceeded their expiration dates and were available for use. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Surveyor 35659 Through a review of new instrument validation documentation for the Sysmex 1000-i hematology analyzer, laboratory policy and procedure and interview with laboratory staff, it was determined the laboratory adopted a reportable range for hematocrit greater than the reportable range established by the manufacturer. Survey findings follow: A. Review of instrument validation records revealed that the laboratory installed the new Sysmex 1000 i hematology analyzer in December of 2016 and performed new instrument validation at that time. B. Review of the laboratory policy and procedure revealed that the laboratory adopted a reportable range upper limit for hematocrit of 71.9% C. Review of the new instrument validation documentation for the Sysmex 1000-i hematology analyzer revealed that the manufacturer established a reportable range for hematocrit on the Sysmex 1000-i hematology analyzer of up to a maximum of 60%. D. In an interview on 1/3/18 at approximately 1500, the technical consultant identified as number 2 on the CMS 209 form confirmed that the reportable range was cited in policy and procedure as 71.9 and was in error. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. |

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| | This STANDARD is not met as evidenced by:<br>Surveyor 35659 Through reveiw of quality control reports, manuafacturer's instrument manual for the Sysmex 1000i, the quality control tables in the Sysmex 1000i instrument, and interview it was determined that the laboratory failed to establish criteria for acceptability of quality control results as instructed by the instrument manufacturer and in such a way as to allow detection of errors in test performance in six of twelve weeks of quality control records reviewed. Findings follow: A. Review of quality control reports for February 2017 for E-check XS hematology controls lot #'s 63550804, 63550805, and 63550806 revealed that the upper limit of acceptability for all analytes for all controls was defined as two times the target value provided by the manufacturer and the lower limit of acceptability for all analytes for all controls was defined as 0.00. B. Review of quality control reports for October 2017 for E-check XS hematology controls lot #'s 72690804, 72690805, and 72690806 for the dates of 10/19/17 to 10/31/17 revealed that the upper limit of acceptability for all analytes for all controls was defined as two times the target value provided by the manufacturer and the lower limit of acceptability for all analytes for all controls was defined as 0.00. C. Review of the manufacturer's manual for the Sysmex 1000i hematology analyzer revealed that users were instructed to enter three times the laboratory's historic CV% in the instrument table for quality control acceptable limits. D. Review of the quality control reports for February 2017, May 2017, and October 2017 revealed that CV% for the various analytes in CBC testing ranged from 0.6% to 9.1%. E. In a tour of the laboratory on 1/3/17 at approximately 1500, the quality control table in the Sysmex 1000i analyzer was observed set at 100% which would have had the effect of setting acceptable upper limits for quality control as two times the quality control target value and the acceptable lower limits for quality control as 0.00. F. In an interview on 1/3/18 at approximately 1515, the technical consultant identified as number 2 on the CMS 209 form confirmed that the acceptable quality control limits for February 2017 and 10/19/17 through 10/31/17 were not correctly set and were not able to reliably determine errors in the test performance. |