Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461164	05/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Acadia General Hospital	1305 Crowley Rayne Highway, Crowley, LA	

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
D0000	A CERTIFICATION SURVEY was performed at Acadia General Hospital - CLIA # 19D0461164 on May 8, 2018 through May 11, 2018. Acadia General Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems. 42 CFR 493.1403 CONDITION: Laboratory Director performing moderate complexity testing. 42 CFR 493.1441 CONDITION: Laboratory Director performing high complexity testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for four (4) of forty seven (47) patients reviewed. Refer to D5411. 2. The laboratory failed to ensure that blood collection tubes are not used beyond their expiration dates. Refer to D5417 I. 3. The laboratory failed to ensure that Blood Bank Quality Control Materials are not used beyond their expiration dates. Refer to D5417 II. 4. The laboratory failed to ensure that the current ISI value was being utilized in the calculation for the International Normalized Ratio (INR) for six (6) of eight (8) patients reviewed. Refer to D5545. 5. The laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient

	testing each day of patient testing, for two (2) of three hundred and ninety three (393) patient test days reviewed. Refer to D5551 6. The laboratory failed to assure the quarterly blood bank alarm verification procedures are performed, for one (1) of six (6) quarters for the Blood Bank Refrigerator, Blood Bank Freezer and Platelet Agitator /Incubator. Refer to D5555. 7. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Refer to D5791.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for four (4) of forty seven (47) patients reviewed. Findings: 1. Observation by the surveyor on May 8, 2018 revealed the laboratory was performing Ammonia testing on the Siemens Dimension EXL Chemistry Analyzer. 2. Review of the Siemens Dimension Ammonia Application Sheet revealed that samples are to be analyzed within 30 minutes." 3. Review of a random selection of patient records for Ammonia testing from January 1, 2017 through May 8, 2018 revealed the laboratory did not analyze Ammonia samples within 30 minutes for the following four (4) patients: On January 22, 2018 Patient 23 was collected at 16:29 PM, and analyzed at 17:16 PM - exceeding the thirty (30) minutes by seventeen (17) minutes. On August 4, 2017 Patient 24 was collected at 12: 15 PM, and analyzed at 13:00 PM - exceeding the thirty (30) minutes by fifteen (15 minutes. On August 14, 2017 Patient 25 was collected at 13:49 PM, and analyzed at 14:33 - exceeding the thirty (30) minutes by thirteen (13) minutes. On July 24, 2017 Patient 26 was collected at 06:33 AM, and analyzed at 07:16 AM - exceeding the thirty (30) minutes by thirteen (13) minutes. 4. Interviews with Personnel 2 on May 10, 2018 confirmed the above patient samples were not analyzed for Ammonia within 30 minutes for the four (4) patients cited.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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. This STANDARD is not met as evidenced by: I. Based on observation, and interview with laboratory personnel, the laboratory failed to ensure that blood collection tubes are not used beyond their expiration dates. Findings: 1. Observation by the surveyors during the tour of the laboratory on May 8, 2018 revealed the following expired blood collection tubes found in phlebotomist trays utilized for collecting patient samples for laboratory testing: Three (3) Becton Dickinson Vacutainer Buff Na Citrate 0.109M 3.2% (blue top) blood collection tubes

- lot number 7256760 with an expiration date of 2018-03-31. Seven (7) Microtainer (purple top) capillary blood collection tubes - lot number 6277865 with an expiration date of 2018-03-31. 2. Interview with personal 2 on May 8, 2018 confirmed by observation the items were expired and in place for patient testing. II. Based on record review, and interview with laboratory personnel, the laboratory failed to ensure that Blood Bank Quality Control Materials are not used beyond their expiration dates. Findings: 1. Review of Blood Bank Quality Control Records from January 1, 2017 through May 8, 2018 revealed the laboratory documented the use of the following expired Quality Control Material for the following dates: From January 7, 2017 through January 11, 2017 the laboratory documented the use of the Quality Control Cell Lot number 44021 with an expiration date of January 16, 2017. From April 1, 2017 through April 13, 2017 the laboratory documented the use of Quality Control Cell lot number 04916 with an expiration date of March 31, 2017. From May 15, 2017 through May 18, 2017 the laboratory documented the use of the Quality Control Serum Lot number 134038-3 with an expiration date of May 14, 2017. From October 14, 2017 through October 18, 2017 the laboratory documented the use of Quality Control Cell lot number 32243 with an expiration date of October 13, 2017. From November 11, 2017 through November 15, 2017 the laboratory documented the use of the Quality Control Cell Lot number 36287 with an expiration date of November 10, 2017. From December 9, 2017 through December 13, 2017 the laboratory documented the use of Quality Control Cell lot number 40333 with an expiration date of December 8, 2017. From January 6, 2018 through January 10, 2018 the laboratory documented the use of the Quality Control Cell Lot number 44378 with an expiration date of January 5, 2018. From February 3, 2018 through February 7, 2018 the laboratory documented the use of Quality Control Cell lot number 48111 with an expiration date of February 2, 2018. From February 24, 2018 through February 28, 2018 the laboratory documented the use of Quality Control Cell lot number 51149 with an expiration date of February 23, 2018. From March 24, 2018 through March 28, 2018 the laboratory documented the use of the Quality Control Cell Lot number 03107 with an expiration date of March 23, 2018. From April 21, 2018 through April 25, 2018 the laboratory documented the use of Quality Control Cell lot number 07151 with an expiration date of April 20, 2018. From February 24, 2018 through February 28, 2018 the laboratory documented the use of Quality Control Cell lot number 51149 with an expiration date of February 23, 2018. 2. Review of the Blood Bank Procedure Manual revealed the quality control material is to be performed each day of patient testing and that the quality control material is utilized to assure accurate and reliable test results for ABO, Rh, Antibody Screen(AbScr) and Compatibility (xmatch) testing. Further review of the policy and procedure manual revealed that expired reagents, solutions and quality control material are not to be used for patient testing. 3. Review of patient test records for the timeframe's that expired Quality Control Material was utilized revealed the following patients were tested and reported without ensuring the laboratory utilized quality control material that was not expired. On January 7, 2017: Patients 48, 49 and 50 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC On January 8, 2017: Patients 51 and 52 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 53 had an ABO, Rh and AbScr; Patient 54 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC. On January 9, 2017: Patient 55 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 56 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 57, 58, 59 and 60 had an ABO, Rh and AbScr. On January 10, 2017: Patients 61, 62, 63, and 65 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 64 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 66, 67 and 68 had an ABO, Rh, and AbScr. On January 11, 2017: Patients 69 and 70 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 71 - 77 had an ABO, Rh, and AbScr. On April 1, 2017: Patients 78, and 79

had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC On April 2, 2017: Patient 80 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patient 81 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC ; Patients 82 and 83 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC. On April 3, 2017: Patients 84, 85, 87, 88, 91 and 92 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 86 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC ; Patient 89 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 90 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC. On April 4, 2017: Patients 93 and 94 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC On April 5, 2017: Patients 95 and 96 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 97 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 98 and 99 had an ABO, Rh, and AbScr. On April 6, 2017: Patient 102 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patients 100 and 103 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 101 and 104 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 105 and 106 had an ABO, Rh, and AbScr. On April 7, 2017: Patients 107, 108 and 109 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 120 had an ABO, Rh, and AbScr. On April 8, 2017: Patient 110 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC. On April 9, 2017: Patient 111 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 112 had an ABO, Rh, AbScr and a xmatch for 1 unit of PRBC. On April 10, 2017: Patient 113 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC. On April 11, 2017: Patient 114 had an ABO, Rh, and AbScr. On April 12, 2017: Patient 115 had an ABO, Rh, and AbScr. On April 13, 2017: Patients 116 and 117 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 118 and 119 had an ABO, Rh, and AbScr. On May 15, 2017: Patients 121 and 122 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 123 - 127 had an ABO, Rh, and AbScr. On May 16, 2017: Patient 128 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 129 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 131 and 132 had an ABO, Rh, and AbScr. On May 17, 2017: Patients 133 and 135 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 134 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 136 had an ABO, Rh, and AbScr. On May 18, 2017: Patient 137 had an ABO, Rh, AbScr and xmatch for 8 units of PRBC; Patient 138 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 139, 140 and 141 had an ABO, Rh, and AbScr. On October 16, 2017: Patient 142 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patients 143 and 144 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 145 - 152 had an ABO, Rh, and AbScr. On October 17, 2017: Patients 153 - 157 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 158 had an ABO, Rh, and AbScr. On October 18, 2017: Patient 159 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 160 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 161, 162 and 163 had an ABO, Rh, and AbScr. On November 11, 2017: Patient 164 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC. On November 12, 2017: Patient 165 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC. On November 13, 2017: Patients 166 and 168 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patient 167 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 169 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patients 170 - 173 had an ABO, Rh, and AbScr. On November 14, 2017: Patients 174 - 177 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 178 - 181 had an ABO, Rh, and AbScr. On November 15, 2017: Patients 182, 184 and 185 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patient 183 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patient 187 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 188 had an ABO, Rh, and AbScr. On December 9, 2017: Patients 189 and 190 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 191 had an ABO, Rh, AbScr and xmatch for 5 units of PRBC; Patient 192 had an ABO, Rh, AbScr and

xmatch for 3 units of PRBC; Patient 193 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 194 and 195 had an ABO, Rh, and AbScr. On December 10, 2017: Patients 196 and 197 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 198 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC. On December 11, 2017: Patients 200 - 203 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 199 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 204 - 207 had an ABO, Rh, and AbScr. On December 12, 2017: Patients 214 and 216 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 215 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patients 217 and 218 had an ABO, Rh, and AbScr. On December 13, 2017: Patients 220, 221 and 223 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 219 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patient 222 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 225 - 228 had an ABO, Rh, and AbScr. On January 6, 2018: Patient 229 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC. On January 7, 2018: Patient 232 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 230 and 233 had an ABO, Rh, AbScr and xmatch for 6 units of PRBC; Patient 231 had an ABO, Rh, AbScr and xmatch for 5 units of PRBC; Patient 234 had an ABO, Rh, and AbScr. On January 8, 2018: Patient 236 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 235 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patients 237, 238 and 239 had an ABO, Rh, and AbScr. On January 9, 2018: Patient 241 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 240 had an ABO, Rh, AbScr and xmatch for 5 units of PRBC; Patient 242 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 243, 244 and 245 had an ABO, Rh, and AbScr. On January 10, 2018: Patients 246 - 248 and 250 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 249 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patient 251 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patients 252, 253 and 254 had an ABO, Rh, and AbScr. On February 3, 2018: Patients 255 and 2570 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 256 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 258 had an ABO, Rh, and AbScr. On February 4, 2018: Patient 259 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC. On February 5, 2018: Patients 260 - 263 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 264 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patients 265, 266 and 267 had an ABO, Rh, and AbScr. On February 6, 2018: Patients 268 - 270 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 271 and 272 had an ABO, Rh, and AbScr. On February 7, 2018: Patients 273 and 274 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 275 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patient 276 had an ABO, Rh, and AbScr. On February 24, 2018: Patients 277, 279 and 280 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 281 had an ABO, Rh, AbScr and xmatch for 5 units of PRBC; Patient 278 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC. On February 25, 2018: Patients 283 and 284 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patient 282 had an ABO, Rh, AbScr and xmatch for 5 units of PRBC. On February 26, 2018: Patients 285 and 286 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patients 287 and 288 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 289 - 292 had an ABO, Rh, and AbScr. On February 27, 2018: Patient 294 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 293 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patients 295 and 296 had an ABO, Rh, and AbScr. On February 28, 2018: Patients 298 and 299 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 300 had an ABO, Rh, AbScr and xmatch for 4 units of PRBC; Patient 297 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patients 301 - 304 had an ABO, Rh, and AbScr. On March 24, 2018: Patients 305 and 306 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 307 had an ABO, Rh, and AbScr. On March

	26, 2018: Patient 309 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 308 had an ABO, Rh, AbScr and xmatch for 3 units of PRBC; Patient 310 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 311 and 312 had an ABO, Rh, and AbScr. On March 27, 2018: Patients 313, 314 and 315 had an ABO, Rh, and AbScr. On March 28, 2018: Patient 317 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 316 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patient 318 had an ABO, Rh, and AbScr. On April 21, 2018: Patients 320 and 321 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 319 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC On April 22, 2018: Patient 322 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC. On April 23, 2018: Patient 323 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 324 had an ABO, Rh, AbScr and xmatch for 5 units of PRBC; Patients 325 - 328 had an ABO, Rh, and AbScr. On April 24, 2018: Patients 329, 330, 332, 333, and 334 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 331 had an ABO, Rh, AbScr and xmatch for 8 units of PRBC; Patients 335 and 336 had an ABO, Rh, and AbScr. On April 25, 2018: Patients 337 and 338 had an ABO, Rh, AbScr and xmatch for 2 units of PRBC; Patient 339 had an ABO, Rh, AbScr and xmatch for 1 unit of PRBC; Patients 340 and 341 had an ABO, Rh, and AbScr. 3. Interview with personal 2 on May 9, 2018 confirmed the laboratory documented the utilization of expired Blood Bank Quality Control Material for the dates and patients cited above.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure that the current ISI value was being utilized in the calculation for the International Normalized Ratio (INR) for six (6) of eight (8) patients reviewed. Findings: 1. Observation by surveyors on May 8, 2018 revealed the laboratory utilized the Sysmex CA-1500 Coagulation Analyzer for Prothrombin Time (PT) and INR testing. Further observation by the surveyor on May 10, 2018 revealed the laboratory had an ISI value of 0.99 and a NMPT value of 10.5 in the Sysmex CA-1500 Coagulation Analyzer. Further observation by the surveyor noted that personnel 2 displayed on the Sysmex CA-1500 Coagulation Analyzer Screen the ISI and NMPT values currently being utilized by testing personnel to the surveyor. NOTE: The value for the NMPT matched the study performed by the laboratory; however review of the current Innovin package insert (lot number 539398 with an expiration date of 10/27 /19) being utilized for patient testing revealed the laboratory should be using an ISI value of 0.96. 2. Interview with personnel 2 and 3 on May 10, 2018 revealed they were unaware the ISI value was not correct for the current lot of Innovin being utilized for patient testing. Personnel 2 and 3 revealed the current lot of Innovin was put into use beginning October 10, 2017. 3. Review of the laboratory policy and procedure manual for Prothrombin Time (PT)/ International Normalized Ratio (INR) revealed when a new lot of Innovin is put into use the laboratory is to do a NMPT study and enter that value in the instrument along with the new ISI value taken from the package insert for the instrument to do the calculation if the INR. 4. Review of a random selection of patient test records for PT/INR testing and reporting from July

	13, 2017 through May 2, 2018 revealed the following six (6) patients were tested and reported utilizing the wrong ISI value. On December 25, 2017 Patient 5 had a PT/INR reported at 18:47 PM. On January 1, 2018 Patient 7 had a PT/INR reported at 9:22 AM. On February 7, 2018 Patient 9 had a PT/INR reported at 20:35 PM. On March 2, 2018 Patient 10 had a PT/INR reported at 13:41 PM. On April 2, 2018 Patient 12 had a PT/INR reported at 14:23 PM. On May 2, 2018 Patient 15 had a PT/INR reported at 6:35 AM. 5. Interview with personnel 2 and 3 on May 10, 2018 confirmed the laboratory has been utilizing the wrong ISI value since October 10, 2017 in the Sysmex CA-1500 Coagulation Analyzer in the calculation of the INR value for the patients cited above.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing, for two (2) of three hundred and ninety three (393) patient test days reviewed. Findings: 1. Review of the Laboratory's Blood Bank Procedure Manual revealed that quality controls for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing are to be performed (daily) each day of patient testing, and prior to patient testing. 2. Review of Blood Bank Quality Control Worksheets and patient test records from January 1, 2017 through May 8, 2018 revealed the laboratory failed to perform and document daily quality control prior to patient testing for the following dates and patients: a) On February 2, 2017 - Patients 41 and 44 had an ABO, Rh, AbScr and xmatch for two (2) units of Packed Red Blood Cells (PRBC); Patients 42, 43, 45, and 46 had an ABO, Rh and AbScr. b) On April 29, 2017 - Patient 47 had an ABO, Rh, and AbScr. 3. Review of Quality Assurance records revealed the laboratory failed to identify and take corrective action to ensure there was no outcome to patients. 4. Interview with personnel 2 and 3 on May 9, 2018 confirmed the laboratory failed to perform and document daily quality control prior to patient testing for the dates and patients cited above. Personnel 2 stated there were monitors in place to assure that patient testing was not performed without having quality control performed prior to patient testing; however personnel 2 confirmed the monitors failed to catch the issue cited above.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under

	appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to assure the quarterly blood bank alarm verification procedures are performed, for one (1) of six (6) quarters for the Blood Bank Refrigerator, Blood Bank Freezer and Platelet Agitator/Incubator. Findings: 1. Review of the Blood Bank's Policy and Procedure Manual revealed quarterly alarm checks were to be performed on the blood bank refrigerator, blood bank freezer and the platelet agitator/incubator. 2. Review of the Blood Bank's Circular Temperature Charts from January 1, 2017 through May 9, 2018 revealed the laboratory failed to perform and document the quarterly alarm checks for the Blood Bank Refrigerator, Freezer and Platelet Agitator/incubator for the first quarter in 2017. following two (2) quarters: 3. Interview with personnel 2 and 3 on May 9, 2018 revealed alarm checks are to be performed quarterly; however, they did confirm that the laboratory failed to perform alarm checks for the first quarter in 2017.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for four (4) of forty seven (47) patients reviewed. Refer to D5411. b) The laboratory failed to ensure that blood collection tubes are not used beyond their expiration dates. Refer to D5417 I. c) The laboratory failed to ensure that Blood Bank Quality Control Materials are not used beyond their expiration dates. Refer to D5417 II. d) The laboratory failed to ensure that the current ISI value was being utilized in the calculation for the International Normalized Ratio (INR) for six (6) of eight (8) patients reviewed. Refer to D5545. e) The laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing, for two (2) of three hundred and ninety three (393) patient test days reviewed. Refer to D5551 f) The laboratory failed to assure the quarterly blood bank alarm verification procedures are performed, for one (1) of six (6) quarters for the Blood Bank Refrigerator, Blood Bank Freezer and Platelet Agitator/Incubator. Refer to D5555. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory. However, the laboratory failed to include

	monitors that would correct the issues cited above. 3. Interview with personnel 2 and 3 on May 11, 2018 confirmed the laboratory was unaware of the issues cited above, and failed to capture the problems cited identified during the survey.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D 6021.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for four (4) of forty seven (47) patients reviewed. Refer to D5411. 2. The laboratory failed to ensure that blood collection tubes are not used beyond their expiration dates. Refer to D5417 I. 3. The laboratory failed to ensure that the current ISI value was being utilized in the calculation for the International Normalized Ratio (INR) for six (6) of eight (8) patients reviewed. Refer to D5545.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of patient test records and quality control records indicated problems as follows: a) The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for four (4) of forty seven (47) patients reviewed. Refer to D5411. b) The laboratory failed to ensure that blood collection tubes are not used beyond their expiration dates. Refer to D5417 I. c) The laboratory failed to ensure that the current ISI value was being utilized in the calculation for the International Normalized Ratio (INR) for six (6) of eight (8) patients reviewed. Refer to D5545. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5791. 3. Interview with personnel 11 and the Director of Nursing (DON) on April 5, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Please refer to D6087. 2. The Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D6093. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6094.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure that Blood Bank Quality Control Materials are not used beyond their expiration dates. Refer to D5417 II. 2. The laboratory failed to assure the quarterly blood bank alarm verification procedures are performed, for one (1) of six (6) quarters for the Blood Bank Refrigerator, Blood Bank Freezer and Platelet Agitator/Incubator. Refer to D5555.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, quality control and patient test records and interview with personnel, the Laboratory Director failed to ensure the laboratory documented the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing, for two (2) of three hundred and ninety three (393) patient test days reviewed. Refer to D5551
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Findings: 1. A review of patient test records and quality control records indicated problems found in the analytic systems as follows: a) The laboratory failed to ensure that Blood Bank Quality Control Materials are not used beyond their expiration dates. Refer to D5417 II. b) The laboratory failed to document the performance of quality control testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing, for two (2) of three hundred and ninety three (393) patient test days reviewed. Refer to D5551 c) The laboratory failed to assure the quarterly blood bank alarm verification procedures are performed, for one (1) of six (6) quarters for the Blood Bank Refrigerator, Blood Bank Freezer and Platelet Agitator/Incubator. Refer to D5555. 2. The laboratory had a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify the deficiencies identified. 3. Interview with personnel 2 on May 11, 2018 confirmed the laboratory failed to identify the deficiency cited above.