Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2129156	07/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
The Center For Cancer And Blood Disorders	800 W Magnolia Avenue, Fort Worth, TX	

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	Entrance and exit conferences were held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The laboratory representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory Alternate Assessment Proficiency Testing (AAPT) records (2017 and 2018) and staff interview, the laboratory failed to ensure that proficiency test specimen result information from the Beckman Coulter Gallios database was retained. Findings included: 1. Review of the laboratory's Alternate Assessment Proficiency testing records from 2017 and 2018 revealed the laboratory failed to retain proficiency test specimen result information from the Beckman Coulter Gallios database for 2017 Series A Survey (AAPT17-LLA) received on 06/08

	/2017. 2. The laboratory was asked to provide documentation of the proficiency test specimen information. No documentation was provided. The above findings were confirmed by testing person #1 on 07/30/3019 at 1340 hours in the conference room.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of patient records and confirmed in interview, the laboratory failed to document the date and time patient specimens were received into the laboratory for processing and testing. Findings included: 1. A random review of patient records from 2019 revealed the laboratory failed to document the date and time patient specimens were received into the laboratory for flow cytometry processing and testing. The laboratory has an annual volume of 500 flow cytometry tests. 2. During an interview on 07/30/3019 at 0930 hours in the laboratory, testing person #1 was asked if the laboratory documents the date and time a specimen was received. He stated that the laboratory did NOT document the specimen receipt date/time. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy for the Beckman Coulter Gallios reagents, reagent manufacturer's instructions, a random review of laboratory environmental records (01/2018, 03/2018, 04/2018, 05/2018, 03/2019, 04/2019 and 05/2019), and confirmed in interview, the laboratory failed to ensure room temperature ranges were within specification requirements for the Beckman Coulter Gallios reagents for 7 of 7 months. Findings included: 1. Review of the laboratory policy titled "Preparation of Reagents for Processing Bone Marrow Aspirate and Peripheral Blood Specimens for Leukemia and Lymphoma Flow Cytometry Data Acquisition using the Beckman Coulter Gallios Flow Cytometer" stated the following: "5.2 Wash Buffer Working Stock Solutions ....NOTE: Wash buffer is stored at room temperature (18 - 29 C) ... 5.4 1L Lysis Buffer ... .5.4.3.9 NOTE: Bring the lysis buffer to room temperature (18C - 29 C) prior to use." 2. A review of the laboratory's reagent manufacturer's instructions revealed the laboratory utilized the following reagents for flow cytometry testing: a. IOTest Conjugated Antibody CD2 (REF A60784) b. IOTest Conjugated Antibody CD3 (REF A66329) c. IOTest Conjugated Antibody CD4 (REF IM0448U) d. IOTest Conjugated Antibody CD5 (REF A51075) e. IOTest Conjugated Antibody CD7 (REF B06499) f. IOTest Conjugated Antibody CD8 (REF B21205) g. IOTest Conjugated Antibody CD10 (REF IM3633) h. IOTest Conjugated Antibody CD11c

(REF B19719) i. IOTest Conjugated Antibody CD13 (REF IM1427U) j. IOTest Conjugated Antibody CD14 (REF B00846) k. IOTest Conjugated Antibody CD19 (REF IM362U) l. IOTest Conjugated Antibody CD13 (REF A74777) m. IOTest Conjugated Antibody CD22 (REF A89311) n. IOTest Conjugated Antibody CD23 (REF A33099) o. IOTest Conjugated Antibody CD33 (REF IM2471U) p. IOTest Conjugated Antibody CD34 (REF A89309) r. IOTest Conjugated Antibody CD 38 (REF A70205) s. IOTest Conjugated Antibody CD45 (REF A96416) t. IOTest Conjugated Antibody CD56 (IM2073U) u. IOTest Conjugated Antibody CD117 (REF IM3698) v. IOTest FMC7 (REF IM1364U) w. IOTest HLA-DR (REF IM0463U) x. IOTest Anti-Kappa (REF A64828) z. IOTes Anti-Lambda (REF 64827) 3. Review of the manufacturer's instructions for each reagent listed in findings #2 stated the following in the section titled "Storage and Handling Conditions and Stability": "This reagent is stable up to the expiration date when stored at 2-8C. Do not freeze. No reconstitution is necessary. This monoclonal antibody may be used directly from the vial. Bring reagent to 18 - 25C prior to use." 4. Review of the laboratory environmental records (04/2018, 05/2018,03/2019, 04/2019 and 05/2019) revealed the laboratory used a room temperature range of 16 - 32 C. The laboratory failed to ensure room temperature ranges were within the specification requirements for the Beckman Coulter Gallios reagents for 7 of 7 months. 5. The above findings were confirmed by testing person #1 on 07/30/2019 at 1340 hours in the conference room. II. Based on review of laboratory policy for the Beckman Coulter Gallios reagents, reagent manufacturer's instructions, a random review of laboratory environmental records (01 /2018, 03/2018, 04/2018, 05/2018, 03/2019, 04/2019 and 05/2019), and confirmed in interview, the laboratory failed to ensure refrigerator temperature ranges were within the specification requirements for the Beckman Coulter Gallios reagents for 7 of 7 months. Findings included: 1. Review of the laboratory policy titled "Preparation of Reagents for Processing Bone Marrow Aspirate and Peripheral Blood Specimens for Leukemia and Lymphoma Flow Cytometry Data Acquisition using the Beckman Coulter Gallios Flow Cytometer" stated the following: "5.3 RPMI + 10% FBS Working Stock Solution ... .NOTE: Store the three 50 mL aliquot tubes with RPMI + 10% FBS solution in the refrigerator at (2 - 8 C) ... . 5.4 1L Lysis Buffer ... . 5.4.3.9 NOTE: Undiluted and diluted lysis buffer reagent is stored refrigerated at (2 - 8 C)." 2. A review of the laboratory's reagent manufacturer's instructions revealed the laboratory utilized the following reagents for flow cytometry testing: a. IOTest Conjugated Antibody CD2 (REF A60784) b. IOTest Conjugated Antibody CD3 (REF A66329) c. IOTest Conjugated Antibody CD4 (REF IM0448U) d. IOTest Conjugated Antibody CD5 (REF A51075) e. IOTest Conjugated Antibody CD7 (REF B06499) f. IOTest Conjugated Antibody CD8 (REF B21205) g. IOTest Conjugated Antibody CD10 (REF IM3633) h. IOTest Conjugated Antibody CD11c (REF B19719) i. IOTest Conjugated Antibody CD13 (REF IM1427U) j. IOTest Conjugated Antibody CD14 (REF B00846) k. IOTest Conjugated Antibody CD19 (REF IM362U) l. IOTest Conjugated Antibody CD13 (REF A74777) m. IOTest Conjugated Antibody CD22 (REF A89311) n. IOTest Conjugated Antibody CD23 (REF A33099) o. IOTest Conjugated Antibody CD33 (REF IM2471U) p. IOTest Conjugated Antibody CD34 (REF A89309) r. IOTest Conjugated Antibody CD 38 (REF A70205) s. IOTest Conjugated Antibody CD45 (REF A96416) t. IOTest Conjugated Antibody CD56 (IM2073U) u. IOTest Conjugated Antibody CD117 (REF IM3698) v. IOTest FMC7 (REF IM1364U) w. IOTest HLA-DR (REF IM0463U) x. IOTest Anti-Kappa (REF A64828) z. IOTes Anti-Lambda (REF 64827) 3. Review of the manufacturer's instructions for each reagent listed in findings #2 stated the following in the section titled "Storage and Handling Conditions and Stability": "This reagent is stable up to the expiration date when stored at 2-8C. Do not freeze. No reconstitution is necessary. This monoclonal antibody may be used directly from the vial." 4. Review of the

	laboratory environmental records (01/2018, 03/2018, 04/2018, 05/2018, 03/2019, 04 /2019 and 05/2019), revealed the laboratory used a refrigerator temperature range of 2 - 10 C. The laboratory failed to ensure refrigerator temperature ranges were within the specification requirements of 2 - 8 C for the Beckman Coulter Gallios reagents for 5 of 5 months. 5. The above findings were confirmed by testing person #1 on 07/30 /2019 at 1340 hours in the conference room.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and in interview with staff, the laboratory director failed to ensure policies were established and competency assessment was maintained for individuals who perform high complexity testing, as evidenced by: 1. The laboratory failed to evaluate and document performance of 1 of 1 Testing Persons responsible for high complexity testing at least semiannually during the first year testing persons analyze patient specimens in 2017. Refer to D6127. 2. The laboratory failed to perform the annual competency evaluations for 1 of 1 testing persons for the high complexity testing in the specialty of hematology in 2018. Refer to D6128
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, laboratory's personnel records, review of testing personnel competency assessment documentation, and staff interview, the technical supervisor failed to perform and document direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing for 1 of 1 testing persons in 2017. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. 2. Review of personnel records from 09/2016 through 07/30/2019 revealed the following: Testing Person #2; Date of hire-09/12 /2016; Termination date-01/09/2019 (Testing person #2 was the only testing person during this time period.) 3. Review of the competency assessment document revealed the following: "Assessment Period-6 month Trainee-Testing Person #2; Signed 04/16 /2018 (This signature is dated 1 year after assessment) Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences; Signed 04/10 /2017 Module 1: Flow Cytometry Instrument Start up/Shutdown and PMs; Method of Training-Verbal Review Module 2: Reagent Preparation; Method of Training-Verbal

	Review (No Module) Module 4: Leukemia/Lymphoma Antibody Cocktail Preparation; Method of Training-Verbal Review Module 5: Determination of Cell Counts and Viability; Method of Training-Verbal Review Module 6: Specimen Preparation and Antibody Staining/LMD File Transfer; Method of Training-Verbal Review Module 7: Flow Cytometry Instrument Linearity; Method of Training-Verbal Review Module 8: Reagent/Laboratory Maintenance and Safety; Method of Training-Verbal Review Module 9: Flow Cytometry Equipment Maintenance; Method of Training-Verbal Review Module 10: Gallios Flow Cytometer QC; Method of Training-Verbal Review Module 11: Specimen Management: Method of Training-Verbal Review" 4. In an interview on 07/30/2019 at 0930 in the laboratory, testing person #1 was asked what the laboratory's affiliation was with Miraca Life Sciences. He stated that Miraca Life Sciences experienced a change of ownership in the third quarter of 2107 and is now Inform Diagnostics. He stated that he performs the flow cytometry testing on specimens and Inform Diagnostics performs the "professional component" of the testing. Inform Diagnostics evaluates the specimen data. 5. In an interview via email on 07/30/2019 at 1323 hours, the Flow Cytometry Partnership Supervisor for Miraca Life Sciences (now Inform Diagnostics), stated, "Testing person #2's 6-month competency was performed verbally via phone call with Inform Diagnostics employee (Flow Cytometry Laboratory Partnership Senior Technical Liaison). Format is question and answer with detailed explanation of procedure from the flow tech." The Flow Cytometry Laboratory Partnership Senior Technical was NOT listed on the laboratory's CMS 209 as the Technical Supervisor. The TS listed on the CMS 209 failed to perform and document direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing. Word Key: PM=Preventive Maintenance LMD=List Mode QC=Quality Control
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, laboratory's personnel records, review of testing personnel competency assessment documentation, and staff interview, the technical supervisor failed to document monitoring, recording, and reporting of test results for 1 of 1 testing persons in 2017. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. 2. Review of personnel records from 09/2016 through 07/30 /2019 revealed the following: Testing Person #2; Date of hire-09/12/2016; Termination date-01/09/2019 (Testing person #2 was the only testing person during this time period.) 3. Review of the competency assessment document revealed the following: "Assessment Period-6 month Trainee-Testing Person #2; Signed 04/16 /2018 (This signature is dated 1 year after assessment) Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences; Signed 04/10 /2017 Module 1: Flow Cytometry Instrument Start up/Shutdown and PMs; Method of Training-Verbal Review Module 2: Reagent Preparation; Method of Training-Verbal Review (No Module) Module 4: Leukemia/Lymphoma Antibody Cocktail Preparation; Method of Training-Verbal Review Module 5: Determination of Cell Counts and Viability; Method of Training-Verbal Review Module 6: Specimen Preparation and Antibody Staining/LMD File Transfer; Method of Training-Verbal

	Review Module 7: Flow Cytometry Instrument Linearity; Method of Training-Verbal Review Module 8: Reagent/Laboratory Maintenance and Safety; Method of Training-Verbal Review Module 9: Flow Cytometry Equipment Maintenance; Method of Training-Verbal Review Module 10: Gallios Flow Cytometer QC; Method of Training-Verbal Review Module 11: Specimen Management: Method of Training-Verbal Review" 4. In an interview on 07/30/2019 at 0930 in the laboratory, testing person #1 was asked what the laboratory's affiliation was with Miraca Life Sciences. He stated that Miraca Life Sciences experienced a change of ownership in the third quarter of 2107 and is now Inform Diagnostics. He stated that he performs the flow cytometry testing on specimens and Inform Diagnostics performs the "professional component" of the testing. Inform Diagnostics evaluates the specimen data. 5. In an interview via email on 07/30/2019 at 1323 hours, the Flow Cytometry Partnership Supervisor for Miraca Life Sciences (now Inform Diagnostics), stated, "Testing person #2's 6-month competency was performed verbally via phone call with Inform Diagnostics employee (Flow Cytometry Laboratory Partnership Senior Technical Liaison). Format is question and answer with detailed explanation of procedure from the flow tech." The Flow Cytometry Laboratory Partnership Senior Technical was NOT listed on the laboratory's CMS 209 as the Technical Supervisor. The TS listed on the CMS 209 failed to document monitoring, recording, and reporting of test results for 1 of 1 testing persons in 2017.
D6123	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, laboratory's personnel records, review of testing personnel competency assessment documentation, and staff interview, the technical supervisor failed to document review of preliminary results, worksheets, quality control, proficiency testing, and preventative maintenance for 1 of 1 testing persons in 2017. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. 2. Review of personnel records from 09/2016 through 07/30/2019 revealed the following: Testing Person #2; Date of hire-09/12/2016; Termination date-01/09/2019 (Testing person #2 was the only testing person during this time period.) 3. Review of the competency assessment document revealed the following: "Assessment Period-6 month Trainee-Testing Person #2; Signed 04/16/2018 (This signature is dated 1 year after assessment) Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences; Signed 04/10/2017 Module 1: Flow Cytometry Instrument Start up/Shutdown and PMs; Method of Training-Verbal Review Module 2: Reagent Preparation; Method of Training-Verbal Review (No Module) Module 4: Leukemia/Lymphoma Antibody Cocktail Preparation; Method of Training-Verbal Review Module 5: Determination of Cell Counts and Viability; Method of Training-Verbal Review Module 6: Specimen Preparation and Antibody Staining/LMD File Transfer; Method of Training-Verbal Review Module 7: Flow Cytometry Instrument Linearity; Method of Training-Verbal Review Module 8: Reagent/Laboratory Maintenance and Safety; Method of Training-Verbal Review Module 9: Flow Cytometry Equipment Maintenance; Method of Training-Verbal Review Module 10: Gallios Flow Cytometer QC; Method of Training-Verbal Review Module 11:

	Specimen Management: Method of Training-Verbal Review" 4. In an interview on 07 /30/2019 at 0930 in the laboratory, testing person #1 was asked what the laboratory's affiliation was with Miraca Life Sciences. He stated that Miraca Life Sciences experienced a change of ownership in the third quarter of 2107 and is now Inform Diagnostics. He stated that he performs the flow cytometry testing on specimens and Inform Diagnostics performs the "professional component" of the testing. Inform Diagnostics evaluates the specimen data. 5. In an interview via email on 07/30/2019 at 1323 hours, the Flow Cytometry Partnership Supervisor for Miraca Life Sciences (now Inform Diagnostics), stated, "Testing person #2's 6-month competency was performed verbally via phone call with Inform Diagnostics employee (Flow Cytometry Laboratory Partnership Senior Technical Liaison). Format is question and answer with detailed explanation of procedure from the flow tech." The Flow Cytometry Laboratory Partnership Senior Technical was NOT listed on the laboratory's CMS 209 as the Technical Supervisor. The TS listed on the CMS 209 failed to document review of preliminary results, worksheets, quality control, proficiency testing, and preventative maintenance for 1 of 1 testing persons in 2017.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, laboratory's personnel records, review of testing personnel competency assessment documentation, and staff interview, the technical supervisor failed to document direct observation of performance of instrument maintenance and function checks for 1 of 1 testing persons in 2017. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. 2. Review of personnel records from 09/2016 through 07/30/2019 revealed the following: Testing Person #2; Date of hire-09/12/2016; Termination date-01/09/2019 (Testing person #2 was the only testing person during this time period.) 3. Review of the competency assessment document revealed the following: "Assessment Period-6 month Trainee-Testing Person #2; Signed 04/16/2018 (This signature is dated 1 year after assessment) Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences; Signed 04/10/2017 Module 1: Flow Cytometry Instrument Start up /Shutdown and PMs; Method of Training-Verbal Review Module 2: Reagent Preparation; Method of Training-Verbal Review (No Module) Module 4: Leukemia /Lymphoma Antibody Cocktail Preparation; Method of Training-Verbal Review Module 5: Determination of Cell Counts and Viability; Method of Training-Verbal Review Module 6: Specimen Preparation and Antibody Staining/LMD File Transfer; Method of Training-Verbal Review Module 7: Flow Cytometry Instrument Linearity; Method of Training-Verbal Review Module 8: Reagent/Laboratory Maintenance and Safety; Method of Training-Verbal Review Module 9: Flow Cytometry Equipment Maintenance; Method of Training-Verbal Review Module 10: Gallios Flow Cytometer QC; Method of Training-Verbal Review Module 11: Specimen Management: Method of Training-Verbal Review" 4. In an interview on 07/30/2019 at 0930 in the laboratory, testing person #1 was asked what the laboratory's affiliation was with Miraca Life Sciences. He stated that Miraca Life Sciences experienced a change of ownership in the third quarter of 2107 and is now Inform Diagnostics. He

	stated that he performs the flow cytometry testing on specimens and Inform Diagnostics performs the "professional component" of the testing. Inform Diagnostics evaluates the specimen data. 5. In an interview via email on 07/30/2019 at 1323 hours, the Flow Cytometry Partnership Supervisor for Miraca Life Sciences (now Inform Diagnostics), stated, "Testing person #2's 6-month competency was performed verbally via phone call with Inform Diagnostics employee (Flow Cytometry Laboratory Partnership Senior Technical Liaison). Format is question and answer with detailed explanation of procedure from the flow tech." The Flow Cytometry Laboratory Partnership Senior Technical was NOT listed on the laboratory's CMS 209 as the Technical Supervisor. The TS listed on the CMS 209 failed to document direct observation of performance of instrument maintenance and function checks for 1 of 1 testing persons in 2017.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, laboratory's personnel records, review of testing personnel competency assessment documentation, and staff interview, the technical supervisor failed to perform and document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 1 of 1 testing persons in 2017. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. 2. Review of personnel records from 09/2016 through 07/30/2019 revealed the following: Testing Person #2; Date of hire-09/12/2016; Termination date-01/09/2019 (Testing person #2 was the only testing person during this time period.) 3. Review of the competency assessment document revealed the following: "Assessment Period-6 month Trainee-Testing Person #2; Signed 04/16/2018 (This signature is dated 1 year after assessment) Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences; Signed 04/10/2017 Module 1: Flow Cytometry Instrument Start up/Shutdown and PMs; Method of Training-Verbal Review Module 2: Reagent Preparation; Method of Training-Verbal Review (No Module) Module 4: Leukemia/Lymphoma Antibody Cocktail Preparation; Method of Training-Verbal Review Module 5: Determination of Cell Counts and Viability; Method of Training-Verbal Review Module 6: Specimen Preparation and Antibody Staining/LMD File Transfer; Method of Training-Verbal Review Module 7: Flow Cytometry Instrument Linearity; Method of Training-Verbal Review Module 8: Reagent/Laboratory Maintenance and Safety; Method of Training-Verbal Review Module 9: Flow Cytometry Equipment Maintenance; Method of Training-Verbal Review Module 10: Gallios Flow Cytometer QC; Method of Training-Verbal Review Module 11: Specimen Management: Method of Training-Verbal Review" 4. In an interview on 07 /30/2019 at 0930 in the laboratory, testing person #1 was asked what the laboratory's affiliation was with Miraca Life Sciences. He stated that Miraca Life Sciences experienced a change of ownership in the third quarter of 2107 and is now Inform Diagnostics. He stated that he performs the flow cytometry testing on specimens and Inform Diagnostics performs the "professional component" of the testing. Inform Diagnostics evaluates the specimen data. 5. In an interview via email on 07/30/2019 at

	1323 hours, the Flow Cytometry Partnership Supervisor for Miraca Life Sciences (now Inform Diagnostics), stated, "Testing person #2's 6-month competency was performed verbally via phone call with Inform Diagnostics employee (Flow Cytometry Laboratory Partnership Senior Technical Liaison). Format is question and answer with detailed explanation of procedure from the flow tech." The Flow Cytometry Laboratory Partnership Senior Technical was NOT listed on the laboratory's CMS 209 as the Technical Supervisor. The TS listed on the CMS 209 failed to perform and document assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 1 of 1 testing persons in 2017.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, laboratory's personnel records, review of testing personnel competency assessment documentation, and staff interview, the technical supervisor failed to document assessment of problem solving skills for 1 of 1 testing persons in 2017. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. 2. Review of personnel records from 09/2016 through 07/30/2019 revealed the following: Testing Person #2; Date of hire-09/12/2016; Termination date-01/09/2019 (Testing person #2 was the only testing person during this time period.) 3. Review of the competency assessment document revealed the following: "Assessment Period-6 month Trainee-Testing Person #2; Signed 04/16/2018 (This signature is dated 1 year after assessment) Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences; Signed 04/10/2017 Module 1: Flow Cytometry Instrument Start up/Shutdown and PMs; Method of Training-Verbal Review Module 2: Reagent Preparation; Method of Training-Verbal Review (No Module) Module 4: Leukemia/Lymphoma Antibody Cocktail Preparation; Method of Training-Verbal Review Module 5: Determination of Cell Counts and Viability; Method of Training-Verbal Review Module 6: Specimen Preparation and Antibody Staining/LMD File Transfer; Method of Training-Verbal Review Module 7: Flow Cytometry Instrument Linearity; Method of Training-Verbal Review Module 8: Reagent/Laboratory Maintenance and Safety; Method of Training-Verbal Review Module 9: Flow Cytometry Equipment Maintenance; Method of Training-Verbal Review Module 10: Gallios Flow Cytometer QC; Method of Training-Verbal Review Module 11: Specimen Management: Method of Training-Verbal Review" 4. In an interview on 07/30/2019 at 0930 in the laboratory, testing person #1 was asked what the laboratory's affiliation was with Miraca Life Sciences. He stated that Miraca Life Sciences experienced a change of ownership in the third quarter of 2107 and is now Inform Diagnostics. He stated that he performs the flow cytometry testing on specimens and Inform Diagnostics performs the "professional component" of the testing. Inform Diagnostics evaluates the specimen data. 5. In an interview via email on 07/30/2019 at 1323 hours, the Flow Cytometry Partnership Supervisor for Miraca Life Sciences (now Inform Diagnostics), stated, "Testing person #2's 6-month competency was performed verbally via phone call with Inform Diagnostics employee (Flow Cytometry Laboratory Partnership Senior Technical Liaison). Format is question and answer with detailed explanation of procedure from the flow tech." The

	Flow Cytometry Laboratory Partnership Senior Technical was NOT listed on the laboratory's CMS 209 as the Technical Supervisor. The TS listed on the CMS 209 failed to document assessment of problem solving skills for 1 of 1 testing persons in 2017.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to evaluate and document performance of 1 of 1 Testing Persons responsible for high complexity testing at least semiannually during the first year testing persons analyze patient specimens in 2017. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. The CMS 209 also listed the laboratory director as the clinical consultant and the technical supervisor. 2. Review of personnel records from 09/2016 through 07/30/2019 revealed the following: Testing Person #2; Date of hire-09/12/2016; Termination date-01/09 /2019 (Testing person #2 was the only testing person during this time period.) Training documentation dated 12/08/2016. Competency Evaluation Documented as verbal review on 04/10/2017 by Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences. The document was signed was testing person #1 on 04/16/2018 and by the laboratory director on 06/20/2018. (These signatures were dated 1 year after assessment) No other documentation of competency from 04/10/2017 through 12/31/2017. 3. In an interview on 07/30/2019 at 0930 in the laboratory, testing person #1 was asked what the laboratory's affiliation was with Miraca Life Sciences. He stated that Miraca Life Sciences experienced a change of ownership in the third quarter of 2107 and is now Inform Diagnostics. He stated that he performs the flow cytometry testing on specimens and Inform Diagnostics performs the "professional component" of the testing. Inform Diagnostics evaluates the specimen data. The Flow Cytometry Laboratory Partnership Senior Technical was NOT listed on the laboratory's CMS 209 as the Technical Supervisor. The TS listed on the CMS 209 failed to evaluate and document performance at least semiannually during the first year of patient testing.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to perform the

	annual competency evaluations for 1 of 1 testing persons for the high complexity testing in the specialty of hematology. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #2 listed to perform high complexity testing. The CMS 209 also listed the laboratory director as the clinical consultant and the technical supervisor. 2. Review of personnel records from 09/2016 through 07/30 /2019 revealed the following: Testing Person #2; Date of hire-09/12/2016; Termination date-01/09/2019 (Testing person #2 was the only testing person during this time period.) Training documentation dated 12/08/2016. Competency Evaluation Documented as verbal review on 04/10/2017 by Trainer 2-Flow Cytometry Laboratory Partnership Senior Technical Liaison Miraca Life Sciences. The document was signed was testing person #1 on 04/16/2018 and by the laboratory director on 06 /20/2018. (These signatures were dated 1 year after assessment) No other documentation of competency from 04/10/2017 through 01/09/2019. The TS listed on the CMS 209 failed to perform the 2018 annual competency evaluations for testing person #2. 3. In an interview on 07/30/2019 at 1030 hours in the conference room, testing person #1 was asked to provide documentation of 2018 annual competency assessment for Testing Person #2. No documentation was provided. This confirmed the above findings.