Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2188656	11/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bhc, Llc Dba Cryopoint	1533 E Northfield Drive, Suite 300, Brownsburg, IN	

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 Clinical Laboratory Improvement Amendment (CLIA) Complaint Survey was completed on 11/12/2023. It was determined that the following condition-level deficiencies existed: 42 Code of Federal Regulations (CFR) 493.1230 General Laboratory Systems 42 CFR 493.1250 Analytic Systems 42 CFR 493.1487 High complexity Testing Personnel
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview the laboratory failed to meet the following general laboratory systems requirements: The laboratory failed to have policies and procedures in place to verify the accuracy of one of one analyte (semen analysis) at least twice annually (Refer to D5217); and the laboratory failed to have policies and procedures in place to monitor quality assessment activities for one of one analyte (semen analysis) (Refer to D5291).
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have policies and procedures in place to verify the accuracy of one of one analyte (semen analysis) at least twice annually. Findings include: 1) Review of Standard Operating Procedures for Sperm Processing CPLSP-15003 to CPLSP.15014 with implementation dates 8/25 /2023, 9/7/2023, and 10/20/2023 indicated there were no procedures to verify the accuracy of one of one analyte (semen analysis) at least twice annually. 2) In interview on 11/21/23 at 2:16 pm, SP-1 (Vice President of Regulatory) confirmed there were no policies and procedures for proficiency testing (twice annual verification of accuracy). 3) Total test volume for semen analysis from Aug 2023 to the date of survey =160 tests.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have policies and procedures in place to monitor quality assessment activities for one of one analyte (semen analysis). Findings include: 1) Review of Standard Operating Procedures for Sperm Processing CPLSP-15003 to CPLSP.15014 with implementation dates 8/25 /2023, 9/7/2023, and 10/20/2023 indicated there were no procedures to monitor, assess, and correct problems for semen analysis testing performed. 2) In interview on 11/21/23 at 2:16 pm, SP-1 (Vice President of Regulatory) confirmed there were no policies and procedures for quality assessments monitoring and correction of problems identified. 3) Total test volume for semen analysis from Aug 2023 to the date of survey =160 tests.
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, lack of documentation, record review and interview the laboratory failed to meet the following analytic system requirements: the laboratory failed to have policies and procedures to perform and document maintenance activities for two of two instruments (microscope Nikon: YS2-T/Serial number 15069 and Makler Counting Chamber/Equipment Identification number CPEQ1812) used

	for performing testing on one of one analyte (semen analysis) (Refer to D5429); and the laboratory failed to have policies to perform and document quality control activities for one of one analyte, semen analysis (Refer to D5441).
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: Based on observation, lack of documentation, record review and interview the laboratory failed to have policies and procedures to perform and document maintenance activities for two of two instruments (microscope Nikon: YS2-T/Serial number 15069 and Makler Counting Chamber/Equipment Identification number CPEQ1812) used for performing testing on one of one analyte, semen analysis Findings include: 1) During tour of the laboratory on 11/21/23 at 12:12 pm, the following instruments were observed to be in use for semen analysis; Nikon: YS2-T /Serial number150649 and Makler Counting Chamber/Equipment Identification number CPEQ1812. 2) Upon request for maintenance documentation the Nikon and Makler Counting Chamber on 11/21/2023 at 12:12 pm, SP-1 (Vice President of Regulatory) confirmed none was available. 3) Review of Standard Operating Procedures for Sperm Processing CPLSP-15003 to CPLSP.15014 with implementation dates 8/25/2023, 9/7/2023, and 10/20/2023 indicated there were no procedures to perform or document maintenance activities for the above equipment. 4) In interview on 11/21/23 at 2:16 pm, SP-1 (Vice President of Regulatory) confirmed there were no policies or procedures nor maintenance documentation available for the above equipment. 5) Total test volume for semen analysis from Aug 2023 to the date of survey =160 tests.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation, record review and interview, the laboratory failed to establish quality control procedures and perform quality control for one of one analyte, semen analysis performed on six of six (PT#1-PT#6) patients reviewed. Findings include: 1) Upon request for quality control records on 11/21/2023 at 1:24 pm, SP-1(Vice President of Regulatory) confirmed quality control was not performed

	for the patients reviewed. 2) Medical record review indicated the following patients (PT#1-PT#6) were reported for semen analysis without any quality control performed: PT# Date Staff Person 1 9-6-23 SP-4 2 10-3-23 SP-4 3 11-3-23 SP-4 4 9-14-23 SP-6 5 10-6-23 SP-6 6 11-10-23 SP-6 (PT=patients)/(SP=staff person) 3) Review of Standard Operating Procedures for Sperm Processing CPLSP-15003 to CPLSP.15014 with implementation dates 8/25/2023, 9/7/2023, and 10/20/2023 indicated there were no procedures for quality control activities. 3) In interview on 11/21/23 at 1:24 pm, SP-1 (Vice President of Regulatory) confirmed there were no quality control procedures established nor documented for semen analysis. 4) Total test volume for semen analysis from Aug 2023 to the date of survey =160 tests.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on lack of documentation, record review and interview, the laboratory failed to unsure the high complexity testing personnel met qualification requirements. The laboratory was unable to provide education documentation for two of three testing personnel (SP-4 and SP-6) preforming testing on six of six patients (SP-1 to SP-6) reviewed (Refer to D-6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved

by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on lack of documentation, record review and interview, the laboratory failed to unsure high complexity testing personnel met the qualification requirements. The laboratory was unable to provide education documentation for two of three testing personnel (SP-4 and SP-6) preforming testing on six of six patients (SP-1 to SP-6) reviewed. Findings include: 1) In interview on 11/21/2023 at 10:15 am, SP-1 (Vice President of Regulatory) confirmed the laboraotry was performing high complexity testing (semen analysis-count, concentration, motility, and morphology). 2) Upon request for education documents for SP-4 and SP-6, on 11/21/2023 at 12:34 pm, SP-1 (Vice President of Regulatory) indicated none was available for review. 3) Medical record review indicated the following patients (patients #1-#6) were reported by unqualified laboratory personnel (SP-4 and/or SP-6): (SP=staff person) PT# Date Staff Person 1 9-6-23 SP-4 2 10-3-23 SP-4 3 11-3-23 SP-4 4 9-14-23 SP-6 5 10-6-23 SP-6 6 11-10-23 SP-6 (PT=patients) 4) In interview on 11-21-23 at 12:34 pm, SP-1 confirmed the above patients were reported by staff members whose education documentation could not be verified. 5) Total test volume for semen analysis from Aug 2023 to the date of survey =160 tests.