Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2063166	02/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Direct Path Services, P C	30200 Telegraph Road Suite 405, Bingham Farms, MI	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: . Based on record review and interview with the Manager, the laboratory failed to retain corrective action records as part of its quality assessments for at least 2 years for 17 (February 2020 to July 2021) of 24 months reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation for corrective actions taken when errors have occurred prior to July 2021. 2. An interview on 2/7/22 at 11:32 am with the Manager revealed the laboratory documents corrective actions taken and retains it for 6 months prior to discarding.
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 with the Manager, the laboratory failed to verify the accuracy of its specimen gross examination procedure at least twice annually for 2 (February 2020 to February 2022) of 2 years. Findings include: 1. A review of the laboratory's records revealed a lack of verification of accuracy for the

	laboratory's specimen gross examination procedure at least twice annually. 2. An interview on 2/7/22 at 11:41 am with the Manager revealed the laboratory did not verify the accuracy of its specimen grossing procedure at least twice annually.
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: . Based on observation and interview with the Manager, the laboratory failed to ensure tissue marking dyes did not exceed their expiration date for 2 of 5 tissue marking dyes observed. Findings include: 1. The surveyor observed the following tissue marking dyes during a tour of the laboratory on 2/7/22 at 9:11 am that had exceeded their expiration dates: a. Mercedes Medical Green Tissue Marking Dye expired 12/2019. b. Stat Lab Black Tissue Marking Dye expired 10/21/2021. 2. An interview on 2/7/22 at 9:17 am with the Manager confirmed the tissue marking dyes in use had exceeded their expiration dates.
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 record review and interview with the Manager, the laboratory failed to ensure testing personnel performing high complexity testing met the qualification requirements of 493.1489. Findings include: 1. The laboratory failed to ensure testing personnel were qualified to perform high complexity testing. Refer to D6171.
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 record review and interview with the Manager, the laboratory failed to ensure testing personnel performing high complexity testing were qualified for 1 (Testing Personnel #4) of 5 testing personnel listed on Form CMS-209. Findings include: 1. A review of testing personnel credentials revealed a lack of documentation showing Testing Personnel #4, hired on 8/16/21 and performing specimen gross examinations, was qualified to perform high complexity testing. 2. An interview on 2/7/22 at 12:15 pm with the Manager confirmed Testing Personnel #4 was not qualified to perform high complexity testing. 3. The laboratory was granted 7 days after the survey exit date to submit any additional qualification documentation for Testing Personnel #4 and it was not made available.