DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 01/19/2010
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	32D0534781	A. BUILDING _____ B. WING _____	12/15/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CURTIS BOYD MD PC	522 LOMAS BLVD NE ALBUQUERQUE, NM 87102

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D2016	493.803(a)(b)(c) SUCCESSFUL PARTICIPATION Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Surveyor: 13439 Based on the review of 2008-2009 proficiency test records, manufacturers's instructions and	D2016	Since our lab failed to successfully participate in proficiency testing for Urine hCG and to obtain technical assistance in proficiency testing we were unable to ensure accuracy of the patient test results and are therefore out of Compliance. In our lab, this particular test is used to determine how early a patient might be in a pregnancy. It has always been used in conjunction with a more sensative (quickview) hCG test, a patients Last Menstrual Period, and an ultrasound. It has helped to determine if a patient has had a Miscarriage or is at risk for an Ectopic pregnancy. ① Patient Safety: It has never been used in a given situation as an only test. Therefore it has not imposed immediate jeopardy to the patients health and Safety. ② In order to correct and analyze the proficiency testing I have contacted both Wampole/Iverness and American Proficiency Institute to determine our best plan of Correction regarding the unsuccessful proficiency testing performance. ③ I plan to take every measure needed to make sure our lab is in good standing with CLIA (please see POC specifically for D2105). approved 1/27/10	1/26/10

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Curtis Boyd, M.D. TITLE: owner/medical director (X6) DATE: 1/26/10

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation. Mimi Carthen, CNP lab director 1/26/10

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D2016	Continued From page 1 interview with the technical consultant, the laboratory failed to successfully participate in proficiency testing for the analyte urine hCG. Findings are: 1. The laboratory failed to successfully participate in proficiency testing for hCG. See D2107 2. The laboratory failed to obtain technical assistance or training for proficiency testing failures. See D2105 Since the laboratory failed to successfully participate in proficiency testing, the laboratory could not ensure the accuracy of the patient test results.	D2016	(For detailed Poc please see page 5 of 16 under D2107.)	
D2105	493.843(e) ENDOCRINOLOGY For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by Surveyor: 13439 Based on the review of 2008-2009 proficiency test records, manufacturers's instructions and interview with the technical consultant, the	D2105	approved 1/27/10 Since our failure to comply I have Spoken to Technical Support and a Medical technologist at both wampole/Inverness and American proficiency institute. There is not an indication that the test itself is the problem and both identify that this test is the "ideal" product for our use in our facility. The problem arises in the API proficiency testing. The kit does not pick up hCG lower than 2000 miu/ml and the criteria used by API makes it difficult to test consistently correct. This has been a challenge to achieve 100% accuracy, and in turn threatens our compliance with CLIA API suggests we change our test kit to a lower sensitivity and/or to one	1/26/10

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D2105	Continued From page 2 laboratory failed to obtain training or technical assistance for proficiency testing failures for the analyte urine hCG. Findings are: The laboratory received a score of 60% for the 1st 2 events of 2009. The technical consultant stated at 8:30 am on 12/15/09 that she did not know why the laboratory failed. She also stated that the test kit she used, Wampole Slide hCG, was very effective as a backup to the waived hCG kit the laboratory used when the waived kit results were questionable. The laboratory was enrolled in the American Proficiency Institute's proficiency program for hCG. Review of the proficiency agency's comparative evaluations revealed that the agency set a minimum detection limit for hCG using the Wampole kit at 2000 mU/mL but used referee laboratories within the laboratory's peer group to grade the other laboratories' responses. A review of 2008-2009 proficiency results revealed that proficiency failures occurred because the laboratory was able to detect hCG using the Wampole kit at levels below the proficiency agency's set limit and the laboratory's results disagreed with the reference laboratories results. See D2107 Since the laboratory failed to obtain technical assistance or training for unsuccessful participation in proficiency testing, the laboratory could not ensure the accuracy of the patient testing.	D2105	(Cont) that has controls. Wampole/Inverness has a kit that would fit this Suggestion (without controls) that is called a "Beta hCG Slide Kit" which is a much more sensative test - measuring as low as 500 mIU/ml. Because we already use a quickpak with internal controls this would defeat the purpose of the less sensative hCG Slide in our facility. Any questionable results of this test is backed by a sensative quickpak. See D2107. (For detailed PoC please see page 5 of 16 under D2107).	
D2107	493.843(f) ENDOCRINOLOGY	D2107		

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D2107	Continued From page 3 Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Surveyor: 13439 Based on the review of 2008-2009 proficiency test records, manufacturers's instructions and interview with the technical consultant, the laboratory failed to successfully participate in proficiency testing for the analyte urine hCG. Findings are: 1. The laboratory received a score of 60% for the 1st 2 events of 2009. The technical consultant stated at 8:30 am on 12/15/09 that she did not know why the laboratory failed. She also stated that the test kit she used, Wampole Slide hCG was very effective as a backup to the waived hCG kit the laboratory used when the waived kit results were questionable. 2. The laboratory was enrolled in the American Proficiency Institute's proficiency program for hCG. Review of the proficiency agency's comparative evaluations revealed that the agency set a minimum detection limit for hCG using the Wampole kit at 2000 mU/mL but used referee laboratories within the laboratory's peer group to grade the other laboratories. a. Method Sensitivities (according to the proficiency agency) Inverness (Wampole) UCG SLIDE: 2000 mIU/mL b. The manufacturer's website and package insert stated that the overall accuracy of the kit	D2107	Since our failure to successfully participate in proficiency testing for Urine hCG we have not been able to ensure the accuracy of patient test results. Our plan of Correction has included much debate. This test has always been used in conjunction with more sensative hCG test kit, LMP, and Ultra-Sound. Rather than continuing to risk failure of successfully participating in the API hCG Slide proficiency testing and not being able to show accuracy with consistency - as of 1/25/10 we will no longer use this test in our facility for diagnostic purpose. Instead if there is any question we will send our patients for quantitative hCG blood draw. Staff will be notified at our Staff mtg 1/26/10. (See attached Training record for employees.) Approved 1/27/10 JA	1/25/10

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D2107	Continued From page 4 was 97% and the sensitivity was up to 2 IU/mL (2000 mIU/mL). 3. A review of 2008-2009 proficiency results revealed that proficiency failures occurred because the laboratory was able to detect hCG using the Wampole kit at levels below the proficiency agency's set limit and the laboratory's results disagreed with the reference laboratories results. a. Event 2009-1= 60% These samples were targeted to contain the following amounts of HCG: Sample UCG-01: <2 mIU/mL Sample UCG-02: 46 mIU/mL Sample UCG-03: 2858 mIU/mL- failed by the laboratory Sample UCG-04: <2 mIU/mL Sample UCG-05: 1507 mIU/mL- failed by the laboratory 3 of 51 laboratories reported a positive hCG for Sample UCG-03 when the referee laboratories responses were negative. 1 of 51 laboratories reported a positive hCG for Sample UCG-05 when the referee laboratories responses were negative. b. Event 2009-2 =60% These samples were targeted to contain the following amounts of HCG: Sample UCG-06: 2858 mIU/mL- failed by the laboratory Sample UCG-07: 46 mIU/mL Sample UCG-08: <2 mIU/mL Sample UCG-09: <2 mIU/mL Sample UCG-10: 1507 mIU/mL- failed by the laboratory 3 of 49 laboratories reported a positive hCG for Sample UCG-06 when the referee laboratories responses were negative. 1 of 49 laboratories reported a positive hCG for	D2107	Plan of Correction D2016, D2105 and D2107: In the event of a failed test with American Proficiency Institute our plan of correctron will include: ① Assess if patients were directly affected in this instance. ② Check to see if the QC was performed for the day and documented. ③ Assess for clerical errors in paperwork, transcriptions of results and that the results were read and interpreted correctly. ④ Assess for any signs of improper handling of reagents or any lab deviations have been reported. ⑤ Call API for information and guidance regarding overall results of peer group responses. ⑥ Initiate and document Communication with Staff if necessary.	1/26/10

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D2107	Continued From page 5 Sample UCG-10 when the referee laboratories responses were negative. c. Event 2009-3= 80% These samples were targeted to contain the following amounts of HCG: Sample UCG-11: 1507 mIU/mL Sample UCG-12: 2858 mIU/mL-failed by the laboratory Sample UCG-13: <2 mIU/mL Sample UCG-14: 46 mIU/mL Sample UCG-15: 540 mIU/mL 1 of 49 laboratories reported a positive hCG for Sample UCG-12 when the referee laboratories responses were negative. d. 2008-1= 80% These samples were targeted to contain the following amounts of HCG: Sample UCG-01: <2 mIU/mL Sample UCG-02: 2556 mIU/mL Sample UCG-03: 33 mIU/mL Sample UCG-04: 1236 mIU/mL- failed by the laboratory Sample UCG-05: <2 mIU/mL 4 of 56 laboratories reported a positive hCG for Sample UCG-04 when the referee laboratories responses were negative. e. 2008-2 = 80% These samples were targeted to contain the following amounts of HCG: Sample UCG-06: 2556 mIU/mL Sample UCG-07: 33 mIU/mL Sample UCG-08: <2 mIU/mL Sample UCG-09: 556 mIU/mL- failed by the laboratory Sample UCG-10: 1236 mIU/mL 1 of 57 laboratories reported a positive hCG for Sample UCG-09 when the referee laboratories responses were negative	D2107		

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D2107	Continued From page 6 f. 2008-3 = 100% These samples were targeted to contain the following amounts of HCG: Sample UCG-11: 33 mIU/mL Sample UCG-12: 2556 mIU/mL Sample UCG-13: <2 mIU/mL Sample UCG-14: 1236 mIU/mL Sample UCG-15: <2 mIU/mL 4 out of 54 laboratories reported a positive result for Sample UCG-14 when the acceptable answer was negative. Since the laboratory failed to successfully participate in proficiency testing, the laboratory could not ensure the accuracy of the patient test results.	D2107		
D5449 510M	493.1256(d)(3)(ii)(g) CONTROL PROCEDURES Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, at least once each day patient specimens are assayed or examined the laboratory must, for each qualitative procedure, include a negative and positive control material. The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Surveyor: 13439 Based on the review of 2008-2009 patient and quality control records, the laboratory failed to perform and document a positive and negative control for each day of Rh patient testing. 168 patient were tested on the days the laboratory failed to perform control materials.	D5449	As of December 15th, 2009 when the discrepancy was determined between patient test results and quality control records not matching I incorporated a revised and combined log for our lab. (Please See attached) By Combining the logs this should alleviate and take care of Any discrepancies we have shown in the past. approved 12/15/10	12/15/09

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D5449	Continued From page 7 Findings are: There was no documentation that the laboratory had performed quality control materials on the following days: February 2008 Quality control was documented last on 2/13/08. 2/14/08 Patients 1-12 were tested. 2/15/08 Patients 13-25 were tested. 2/16/08 Patients 26-37 were tested. November 2008 Quality control was documented last on 11/1/08. 11/5/08 Patient 38 was tested. Quality control was documented last on 11/15/08. 11/19/09 Patients 39-49 were tested. January 2009 Quality control was documented last on 1/24/09. 1/29/09 Patients 50-57 were tested. 1/30/09 Patients 58-77 were tested. 1/31/09 Patients 78-94 were tested. February 2009 Quality control was documented last on 2/7/09. 2/11/09 Patients 95-101 were tested. Quality control was documented last on 2/21/09. 2/25/09 Patients 102-115 were tested. March 2009 Quality control was documented last on 2/28/09. 3/4/09 Patients 116-117 were tested. Quality control was documented last on 3/7/09. 3/11/09 Patients 118-131 were tested. Quality control was documented last on 3/14/09. 3/18/09 Patients 132-139 were tested. April 2009	D5449	As of 1/25/10 Patient charts have been reviewed to determine if there was any negative outcome of not performing the controls on the same day. It does not appear there was any negative outcomes. Enclosed are copies of all patient's cover sheet of charts, tested during the time periods missing appropriate documentation. January 30, 2009 patient #58-77 one patient entered/logged twice and counted as two (please see * by the count on enclosed lab sheet.) January 31, 2009 patient #78-93 again, one patient entered/logged twice and counted as two. please see * by the count on enclosed lab sheet).	1/25/10

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D5449	Continued From page 8 Quality control was documented last on 3/28/09. 4/1/09 Patient 140 was tested. Quality control was documented last on 4/4/09. 4/7/09 Patient 141 was tested. Quality control was documented last on 4/15/09. 4/22/09 Patients 142-144 were tested. Quality control was documented last on 4/25/09. 4/29/09 Patients 145-153 were tested. May 2009 Quality control was documented last on 5/3/09. 5/5/09 Patients 154-162 were tested. October 2009 Quality control was documented last on 10/2/09. 10/7/09 Patients 163-165 were tested. Quality control was documented last on 10/16/09. 10/20/09 Patients 166-168 were tested. Since the laboratory failed to perform quality control materials each day of patient testing the laboratory could not ensure the accuracy of the patient results.	D5449		
D6000	493.1403 LABORATORY DIRECTOR 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: Surveyor: 13439 Based on the review of 2008-2009 proficiency test records, manufacturer instructions, 2009 Rh patent and quality control logs and interview with the technical consultant, the laboratory director failed to provide overall management and direction of the laboratory.	D6000	Effective immediately to ensure that patient test results are accurate and that quality assurance is managed appropriately the current lab director McMcCarthy, CNP will have Dr. Boyd owner/medical director Co-sign on any proficiency testing results that are unsuccessful all of our quality assurance policies and reviews and with over-all management of the lab. This will ensure that the approved corrective action plan is followed and the director responsibilities are followed and maintained.	1/25/10

approved 1/27/10

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D6000	Continued From page 9 Findings are: 1. The laboratory director failed to establish a quality assurance policy to identify failures in the laboratory. See D6022 2. The laboratory director failed to ensure that a corrective action plan was followed for proficiency testing failures. See D6019 Since the laboratory director failed to provide overall management and direction of the laboratory, the laboratory could not ensure that patient test results were accurate.	D6000		
D6019	493.1407(e)(4)(iv) DIRECTOR RESPONSIBILITIES The laboratory director must ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Surveyor: 13439 Based on the review of 2008-2009 proficiency test records, manufacturers's instructions and interview with the technical consultant, the laboratory director failed ensure that an effective corrective action plan was followed and actions documented for proficiency testing failures for the analyte urine hCG. Findings are: 1. The laboratory received a score of 60% for the 1st 2 events of 2009. The technical consultant stated at 8:30 am on 12/15/09 that she did not know why the laboratory failed. She also stated	D6019	Effective Immediately Wampole/Iverness Urine hCG Slide test will no longer be used in our facility. (Please refer to D2016 D2015 D2017). Patients with questionable results from other diagnostic tests (LMP Quickview and Ultrasound) will be sent for bloodwork quantitative hCG levels. approved 1/25/10	1/25/10

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D6019	Continued From page 10 that the test kit she used, Wampole Slide hCG was very effective as a backup to the waived hCG kit the laboratory used when the waived kit results were questionable. 2. The laboratory was enrolled in the American Proficiency Institute's proficiency program for hCG. Review of the proficiency agency's comparative evaluations revealed that the agency set a minimum detection limit for hCG using the Wampole kit at 2000 mU/mL but used referee laboratories within the laboratory's peer group to grade the other laboratories. a. Method Sensitivities (according to the proficiency agency) Inverness (Wampole) UCG SLIDE: 2000 mIU/mL b. The manufacturer's website and package insert stated that the overall accuracy of the kit was 97% and the sensitivity was up to 2 IU/mL (2000 mIU/mL). 3. A review of 2008-2009 proficiency results revealed that proficiency failures occurred because the laboratory was able to detect hCG using the Wampole kit at levels below the proficiency agency's set limit and the laboratory's results disagreed with the reference laboratories results. a. Event 2009-1= 60% These samples were targeted to contain the following amounts of HCG: Sample UCG-01: <2 mIU/mL Sample UCG-02: 46 mIU/mL Sample UCG-03: 2858 mIU/mL- failed by the laboratory Sample UCG-04: <2 mIU/mL Sample UCG-05: 1507 mIU/mL- failed by the laboratory	D6019		

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D6019	Continued From page 11	D6019		

3 of 51 laboratories reported a positive hCG for Sample UCG-03 when the referee laboratories responses were negative.
1 of 51 laboratories reported a positive hCG for Sample UCG-05 when the referee laboratories responses were negative.
b. Event 2009-2 =60%
These samples were targeted to contain the following amounts of HCG:
Sample UCG-06: 2858 mIU/mL- failed by the laboratory
Sample UCG-07: 46 mIU/mL
Sample UCG-08: <2 mIU/mL
Sample UCG-09: <2 mIU/mL
Sample UCG-10: 1507 mIU/mL- failed by the laboratory
3 of 49 laboratories reported a positive hCG for Sample UCG-06 when the referee laboratories responses were negative.
1 of 49 laboratories reported a positive hCG for Sample UCG-10 when the referee laboratories responses were negative.
c. Event 2009-3= 80%
These samples were targeted to contain the following amounts of HCG:
Sample UCG-11: 1507 mIU/mL
Sample UCG-12: 2858 mIU/mL-failed by the laboratory
Sample UCG-13: <2 mIU/mL
Sample UCG-14: 46 mIU/mL
Sample UCG-15: 540 mIU/mL
1 of 49 laboratories reported a positive hCG for Sample UCG-12 when the referee laboratories responses were negative.

d. 2008-1= 80%
These samples were targeted to contain the following amounts of HCG:

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	32D0534781	A. BUILDING _____ B. WING _____	12/15/2009

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CURTIS BOYD MD PC	522 LOMAS BLVD NE ALBUQUERQUE, NM 87102

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6019	Continued From page 12 Sample UCG-01: <2 mIU/mL Sample UCG-02: 2556 mIU/mL Sample UCG-03: 33 mIU/mL Sample UCG-04: 1236 mIU/mL- failed by the laboratory Sample UCG-05: <2 mIU/mL 4 of 56 laboratories reported a positive hCG for Sample UCG-04 when the referee laboratories responses were negative. e. 2008-2 = 80% These samples were targeted to contain the following amounts of HCG: Sample UCG-06: 2556 mIU/mL Sample UCG-07: 33 mIU/mL Sample UCG-08: <2 mIU/mL Sample UCG-09: 556 mIU/mL- failed by the laboratory Sample UCG-10: 1236 mIU/mL 1 of 57 laboratories reported a positive hCG for Sample UCG-09 when the referee laboratories responses were negative f. 2008-3 = 100% These samples were targeted to contain the following amounts of HCG: Sample UCG-11: 33 mIU/mL Sample UCG-12: 2556 mIU/mL Sample UCG-13: <2 mIU/mL Sample UCG-14: 1236 mIU/mL Sample UCG-15: <2 mIU/mL 4 out of 54 laboratories reported a positive result for Sample UCG-14 when the acceptable answer was negative. Since the laboratory director failed to ensure that an effective corrective action plan was followed for unsuccessful participation in proficiency testing, the laboratory failed to identify the cause of the proficiency testing failures.	D6019		

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D6022	493.1407(e(5) DIRECTOR RESPONSIBILITIES The laboratory director must assure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Surveyor: 13439 Based on the review of 2008-2009 patient and quality control records, the laboratory director failed to ensure that a quality control and quality assessment plan was followed to ensure that the laboratory performed quality control materials each day of Rh patient testing. 168 patients were tested on the days the laboratory failed to perform control materials. Findings are: There was no documentation that the laboratory had performed quality control materials on the following days: February 2008 Quality control was documented last on 2/13/08. 2/14/08 Patients 1-12 were tested. 2/15/08 Patients 13-25 were tested. 2/16/08 Patients 26-37 were tested. November 2008 Quality control was documented last on 11/1/08. 11/5/08 Patient 38 was tested. Quality control was documented last on 11/15/08. 11/19/09 Patients 39-49 were tested. January 2009 Quality control was documented last on 1/24/09. 1/29/09 Patients 50-57 were tested. 1/30/09 Patients 58-77 were tested.	D6022	Effective 12/15/09 the current lab director McMcCarthy, CNP will ensure patient test controls and patient test results to be performed accurately and documented appropriately. (please see attached POC for D5449 Copy of new log for Rh testing and controls).	12/15/09

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D6022	Continued From page 14 1/31/09 Patients 78-94 were tested. February 2009 Quality control was documented last on 2/7/09. 2/11/09 Patients 95-101 were tested. Quality control was documented last on 2/21/09. 2/25/09 Patients 102-115 were tested. March 2009 Quality control was documented last on 2/28/09. 3/4/09 Patients 116-117 were tested. Quality control was documented last on 3/7/09. 3/11/09 Patients 118-131 were tested. Quality control was documented last on 3/14/09. 3/18/09 Patients 132-139 were tested. April 2009 Quality control was documented last on 3/28/09. 4/1/09 Patient 140 was tested. Quality control was documented last on 4/4/09. 4/7/09 Patient 141 was tested. Quality control was documented last on 4/15/09. 4/22/09 Patients 142-144 were tested. Quality control was documented last on 4/25/09. 4/29/09 Patients 145-153 were tested. May 2009 Quality control was documented last on 5/3/09. 5/5/09 Patients 154-162 were tested. October 2009 Quality control was documented last on 10/2/09. 10/7/09 Patients 163-165 were tested. Quality control was documented last on 10/16/09. 10/20/09 Patients 166-168 were tested. Since the laboratory director failed to ensure that a quality control and quality assessment plan was followed, the laboratory could not ensure the	D6022		

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D6022	Continued From page 15 accuracy of the patient results on the days that quality control materials were not performed.	D6022		