STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
FACILITY LICENSING AND INVESTIGATIONS SECTION

In Re: BioReference Laboratories, Inc.

CONSENT ORDER

WHEREAS, pursuant to Conn. Gen. Stat. § 19a-30, BioReference Laboratories, Inc. has been issued three (3) licenses by the Connecticut Department of Public Health ("Department") to operate clinical laboratories in Connecticut. The three licensed clinical laboratories are located at 27 Hospital Avenue, Danbury, Connecticut 06810 (CL-0698); 1 Perryridge Road, Greenwich, Connecticut 06830 (CL-0694) and 12 Avery Place, Westport, Connecticut 06880 (CL-0691); and,

WHEREAS, pursuant to Conn. Gen. Stat. § 19a-30 and the Regulations of Connecticut State Agencies §§ 19a-36-D20 through 19a-36-D38, BioReference has been issued an approval by the Department for a blood collection facility in Connecticut. The blood collection facility is located at 2½ Dearfield Drive, Greenwich, Connecticut 06831 (Approval No. DS-0941); and,

WHEREAS, the three licensed clinical laboratories and the blood collection facility which has received a certificate of approval are collectively referred to as "BioReference" or the "Licensees" throughout this Consent Order; and,

WHEREAS, the Facility Licensing and Investigations Section ("FLIS") of the Department commenced an investigation regarding BioReference's three clinical laboratories and the blood collection facility which consisted in part of unannounced inspections on various dates between approximately August 25, 2014 and September 4, 2014; and,

WHEREAS, as part of its investigation, the Department has determined that blood collection facilities in Connecticut have been in operation as part of BioReference's clinical laboratory licenses prior to their

receiving a written certificate of approval to do so by the Department in violation of the Regulations of Connecticut State Agencies §§ 19a-36-D20 through 19a-36-D38; and,

WHEREAS, BioReference admits that the following blood collection facilities (listed below) have operated for the period of time identified without a certificate of approval issued by the Department as required by the statutes and regulations governing clinical laboratory licenses and certificates of approval:

BioReference Laboratories Patient Service Center
435 Montauk Avenue
New London, CT 06320
Dates of Operation without certificate of approval:
January 2, 2013 through August 27, 2014.

BioReference Laboratories Patient Service Center
26 Lafayette Street
Norwich, CT 06360
Dates of Operation without certificate of approval:
November 2012 through August 27, 2014.

BioReference Laboratories Patient Service Center
2247 East Main Street
Waterbury, CT 06705
Dates of Operation without certificate of approval:
July 7, 2014 through August 27, 2014.

BioReference Laboratories Patient Service Center
501 Kings Highway East
Suite 202
Fairfield, CT 06825
Dates of Operation without certificate of approval:
May 10, 2013 through August 27, 2014.

BioReference Laboratories Patient Service Center
158 Main Street
Ansonia, CT 06401
Dates of Operation without certificate of approval:
June 7, 2014 through August 27, 2014.

BioReference Laboratories Patient Service Center
850 N. Main Street
Wallingford, CT 06492

Dates of Operation without certificate of approval:
August 4, 2014 through August 27, 2014.

BioReference Laboratories Patient Service Center
391 Norwich Westerly Road
North Stonington, CT 06359
Dates of Operation without certificate of approval:
August 11, 2014 through August 27, 2014.

BioReference Laboratories Patient Service Center
470 Bridgeport Avenue
Milford, CT 06460
Dates of Operation without certificate of approval:
May 5, 2014 through August 27, 2014.

WHEREAS, BioReference admits that it operated the eight blood collection facilities listed above without a certificate of approval and before the facilities were in regulatory compliance and closed said blood collection facilities as a result of an Interim Cease and Desist Consent Order issued by the Department; and,

WHEREAS, in September of 2014, the Department received a comprehensive plan of correction from BioReference which, upon the effective date of this Consent Order, is hereby accepted by the Department; and,

WHEREAS, on October 20, 2014, BioReference withdrew all of its pending applications for blood collection facilities in Connecticut; and,

WHEREAS, as of the effective date of this Consent Order, BioReference has no pending applications for clinical laboratory licensure and no pending applications for certificates of approval for blood collection facilities.

NOW THEREFORE, the Department acting herein and through Barbara Cass, FLIS Section Chief, and the Licensees, acting herein and through Marc Grodman M.D., its President, hereby stipulate and agree as follows:

1. BioReference's three clinical laboratory licenses and their one certificate of approval for a blood collection facility (collectively "BioReference" or the "Licensee") shall be placed on probation for a period of five years ("probationary period") subject to the following terms:
    a. During the probationary period, the Department shall have sole and absolute discretion regarding whether to issue BioReference any additional clinical laboratory licenses in Connecticut. BioReference waives any rights it may have to challenge such decision in any forum, and agrees that the Department is under no obligation to issue any clinical laboratory licenses during this five year period. BioReference agrees not to operate or own a clinical laboratory in Connecticut without a license issued by the Department.
    b. During the probationary period, the Department shall have sole and absolute discretion regarding whether to issue BioReference a certificate of approval for any blood collection facility in Connecticut. BioReference waives any rights it may have to challenge such decision in any forum, and agrees that the Department is under no obligation to issue any certificates of approval for blood collection facilities during this five year time period. Bioreference agrees not to operate or own a blood collection facility in Connecticut without a certificate of approval issued by the Department.
    c. BioReference agrees that any clinical laboratory or blood collection facility which is granted a license or certificate of approval by the Department during the probationary period shall be placed on probation and subject to the terms of this Consent Order.
    d. Within ten business days of the effective date of this Consent Order, BioReference shall execute a contract with an Independent Consultant ("Consultant"). The Consultant must be pre- approved in writing by the Department. BioReference agrees to fully cooperate with the Consultant. The terms of the contract executed by BioReference with the Consultant shall include all obligations of the Consultant contained in this Consent Order.
    e. The Consultant's duties shall be performed by a single individual unless otherwise approved by the Department. BioReference shall incur all of the costs necessary to comply with this Consent Order, including the cost of the Consultant.
    f. The Consultant shall function in accordance with the FLIS's Consultant Guidelines (Exhibit A - copy attached). The Consultant must be a Medical Laboratory Technologist who holds a minimum of a Bachelor's Degree in Laboratory Science and

certification in medical laboratory science and shall have experience in assessing Quality Assurance and Performance Improvement activities.

g. Within the first thirty (30) days after the execution of the contract with the Independent Consultant, the Consultant shall conduct a review of the three licensed clinical laboratories and the blood collection facility. The Consultant shall confer with the Licensees' Director of Phlebotomy, Laboratory Director, Phlebotomy Manager, and Phlebotomy Supervisor and other staff determined by the Consultant to be necessary to the assessment of care and services and the Licensees' compliance with federal and state statutes and regulations. The Consultant shall issue a report to the Department and BioReference indicating whether the clinical laboratories and the blood collection facility are in statutory and regulatory compliance. Neither BioReference nor the Department shall have an opportunity to review the report prior to its simultaneous release to BioReference and the Department. The report shall identify methods utilized for the analysis, areas reviewed, process, findings and recommendations for securing compliance with regulatory requirements. If BioReference disagrees with any of the findings and recommendations, the Department, the Consultant and BioReference shall meet to discuss the issues. The Department, in its sole and absolute discretion, shall make a final determination regarding the findings and recommendations of the Consultant. Upon approval by the Department of the recommendations of the Consultant, all of the recommendations shall be implemented within a timeframe specified by the Department. Upon completion of the implementation of all of the approved recommendations of the Consultant, Bioreference shall certify such completion to the Department and the Consultant in writing. Within sixty days of such certification, Consultant will make unannounced visits to the Licensees' facilities to determine compliance with the approved recommendations and report the findings of said visits to the Department and BioReference. The Consultant shall act and perform the duties assigned herein at all times to serve the interest of the Department in assuring the safety, welfare and well-being of the patients and patient specimens and to secure compliance with applicable federal and state law and regulations. The Consultant shall not accept any direction or suggestion from the BioReference or its employees that will deter or interfere in fulfilling this obligation. The Consultant shall confer with the

Licensees' Director of Phlebotomy, Laboratory Director, Phlebotomy Manager, and Phlebotomy Supervisor and other staff determined by the Consultant to be necessary to the assessment of services and the Licensees' compliance with federal and state statutes and regulations.

h. The Consultant shall conduct a second review of BioReference within thirty (30) days after the conclusion of the first year of the probationary period, and shall issue a second report, within sixty days after the conclusion of the first year of the probationary period, indicating whether the clinical laboratories and the blood collection facility are in statutory and regulatory compliance. Neither BioReference nor the Department shall have an opportunity to review the report prior to its simultaneous release to BioReference and the Department. The Consultant shall confer with the Licensees' Director of Phlebotomy, Laboratory Director, Phlebotomy Manager, and Phlebotomy Supervisor and other staff determined by the Consultant to be necessary to the assessment of care and services and the Licensees' compliance with federal and state statutes and regulations.

i. The report shall identify methods utilized for the analysis, areas reviewed, process, findings and recommendations. If BioReference disagrees with any of the findings and recommendations, the Department, the Consultant and BioReference shall meet to discuss the issues. The Department, in its sole and absolute discretion, shall make a final determination regarding the findings and recommendations of the Consultant. Upon approval by the Department of the recommendations of the Consultant, all of the recommendations shall be implemented within a timeframe specified by the Department. Upon completion of the implementation of all of the approved recommendations of the Consultant, BioReference shall certify such completion to the Department and the Consultant in writing. Within sixty days of such certification, the Consultant will make unannounced visits to the Licensees' facilities to determine compliance with the approved recommendations and report the findings of said visits to the Department and BioReference.

j. Within one month of the effective date of this Consent Order, the Licensees shall appoint a Phlebotomy Supervisor pre-approved in writing by the Department. The Phlebotomy Supervisor's primary responsibility is the assessment of phlebotomy

procedures and practices provided by phlebotomy staff. The Phlebotomy Supervisor shall be responsible to supervise no more than ten (10) blood collection facilities. The Phlebotomy Supervisor shall visit each blood collection facility every other week for a minimum of twelve (12) months unless the Department identifies through inspections or any other evidence it deems relevant that a longer time period is necessary to ensure substantial compliance with applicable federal and state statutes and regulations. The Phlebotomy Supervisor shall maintain a record of any visit and related issue(s) or problem(s) identified and documentation as to the subsequent action taken to resolve the problem(s). Said records shall be made available to the Department upon request and shall be retained for a minimum of five (5) years. The Phlebotomy Supervisor shall be supervised and monitored by a representative of BioReference, (Director of Phlebotomy and/or Phlebotomy Manager) to ensure the Supervisor is functioning in accordance with this Consent Order and state and federal statutes and regulations and in accordance with standards of practice. Said administrative supervision and oversight shall be provided on a randomized schedule of visits. BioReference shall provide the Phlebotomy Supervisor with the following:

1. A job description, which clearly identifies the supervisor's day-to-day duties and responsibilities; and,
2. An in-service training program, which clearly delineates each Phlebotomy Supervisor's responsibilities and duties with respect to patient and staff observations, interventions and staff remediation.

k. In addition, the Phlebotomy Supervisor shall have the responsibility for:

   1. Assessing, monitoring, and evaluating the delivery of phlebotomy services with particular emphasis and focus on the delivery of services by phlebotomists implementing prompt training and/or remediation in any area in which a staff member demonstrated a deficit. Records of said training and/or remediation shall be maintained by the Licensees for review by the Department and the Consultant;
   2. Assessing, monitoring, and evaluating the coordination of the collection and proper storage of specimens by phlebotomists providing services;

3. Assessing, monitoring, and evaluating environmental conditions which include but are not limited to; cleanliness of equipment, work surfaces, refrigerator and freezer temperature, and storage of biomedical wastes;
4. Assessing, monitoring, and evaluating the infection control program;
5. Assessing, monitoring, and evaluating to ensure the necessary equipment and specimen collection supplies are available and maintained within manufacturer's specifications and expiration date;
6. Assessing, monitoring and evaluating the specimen transportation and delivery procedures;
7. Review all pre-analytical quality issues;
8. Provide BioReference with oversight and resources to implement a responsible and responsive QAPI program; and,
9. Attend QAPI meetings.

l. A QAPI Program shall be maintained by the Licensee, which shall identify a Quality Assurance Performance Improvement Committee, consisting of, at least, the Director of Phlebotomy, Laboratory Director, Phlebotomy Manager, Phlebotomy Supervisor, and phlebotomy staff. The Committee shall meet at least once every thirty (30) days to review all reports or complaints relating to patient care and compliance with federal and state laws and regulations and standards of practice. The activities of the QAPI Committee shall include, but not be limited to, determination and adoption of new policies to be implemented by Licensees' staff to improve patient care practices, and pre-analytical procedures. The Committee shall implement a QAPI program that will measure, track and report on compliance with the requirements of this Consent Order. The Committee shall measure and track the implementation of any changes in the Licensees' policies, procedures, and allocation of resources recommended by the Committee to determine compliance with and effectiveness of such changes. A record of QAPI meetings and subject matter discussed shall be documented and available for review by the Department and the Consultant. Minutes of all such meetings shall be maintained at the facility for a minimum period of five (5) years.

m. The Licensees' Director of Phlebotomy, Laboratory Director, Phlebotomy Manager, and Phlebotomy Supervisor and the Licensees or designee of the Governing Authority shall

meet with the Department quarterly during the first year of the probationary period and at a frequency to be determined after the first year of the probationary period by the Department, in its sole and absolute discretion, for the remainder of the probationary period. The meetings shall include discussions of issues related to the care and services provided by the Licensees and the Licensees' compliance with applicable federal and state statutes and regulations.

n. Any records maintained in accordance with any state or federal law or regulation or as required by this Consent Order shall be made available to the Consultant and the Department, upon request. Except for disclosures to the Consultant, any rights of Licensees to claim and exert privilege to quality assurance or peer review documents under state and/or federal law are preserved and not limited or waived by this Consent Order.

o. Effective upon the execution of this Consent Order, the Licensees, through its Governing Body, Director of Phlebotomy, Laboratory Director, Phlebotomy Manager, and Phlebotomy Supervisor, shall ensure substantial compliance with the following:
   1. Sufficient and qualified personnel are available to meet the needs of the patients;
   2. The Phlebotomy Supervisor is notified in a timely manner of any significant incidents and concerns,
   3. Infection Control, emergency and safety practices are assessed in accordance with current regulations and standards of practice;
   4. Necessary supervision and phlebotomy monitoring is provided to ensure quality care;
   5. Policies and procedures related to the pre-analytical process will be reviewed and revised, and
   6. Equipment and supplies are adequate to meet the needs of the patients.

p. Effectively immediately and upon execution of this Consent Order, the Licensees will notify the Department immediately, if any of the following positions became vacant:
   a. Director of Phlebotomy
   b. Laboratory Director
   c. Phlebotomy Manager
   d. Phlebotomy Supervisor

q. BioReference shall designate a person, pre-approved in writing by the Department, to monitor the requirements of this Consent Order. If this person is unable to fulfill this duty for any reason, BioReference shall designate another individual to fulfill this duty, and the Department must pre-approve this designation in writing prior to that person assuming these responsibilities. During the first year of the probationary period and quarterly for the remainder of the probationary period, the monitor shall issue monthly reports to the Department which describe BioReference's compliance with the terms of the Consent Order.

r. Neither the Licensees nor any beneficial owner of the Licensees shall acquire an existing clinical laboratory in Connecticut without the written approval of the Department during the term of this Consent Agreement.

s. The Licensee shall pay a civil penalty to the Department at the time of signing this Consent Order in the amount of two hundred thousand dollars ($200,000.00), by money order or bank check payable to "Treasurer, State of Connecticut". The civil penalty and any reports required by this Consent Order shall be directed to:

Lori Griffin
Public Health Services Manager
Facility Licensing and Investigations Section
Department of Public Health
410 Capitol Avenue, P.O. Box 340308, MS #12 HSR
Hartford, CT 06134-0308

2. All parties agree that this Consent Order is an Order of the Department with all of the rights and obligations pertaining thereto and attendant thereon. Nothing herein shall be construed as limiting the Department's available legal remedies against the Licensee for violations of the Consent Order or of any other statutory or regulatory requirements, which may be sought in lieu of or in addition to the methods of relief listed above, including all options for the issuance of a statement of charges, the imposition of civil penalties calculated and assessed in accordance with Conn. Gen. Stat. § 19a-30, or any other administrative and judicial relief provided by law.

3. The execution of this Consent Order has no bearing on any criminal liability without the written consent of the Director of the MFCU or the Bureau Chief of the Department of Criminal Justice's Statewide Prosecution Bureau.

4. BioReference agrees that this Consent Order applies only to BioReference's Connecticut operations, and it resolves this matter only on behalf of the Department. BioReference agrees that this Consent Order does not limit any other agency or entity in any manner including but not limited to any actions taken in response to the factual basis of this Consent Order.
5. BioReference agrees that this Consent Order and the terms set forth herein are not subject to reconsideration, collateral attack or judicial review under any form or in any forum including any right to review under the Uniform Administrative Procedure Act, Chapter 368a of the Statutes, Regulations that exists at the time the agreement is executed or may become available in the future, provided that this stipulation shall not deprive BioReference of any other rights that it may have under the laws of the State of Connecticut or of the United States.
6. BioReference agrees that the admissions contained herein are admissible in any subsequent proceeding before the Department in which BioReference's compliance with this Consent Order or state and federal statutes and regulations related to the operation of clinical laboratories and/or blood collection facilities are at issue.
7. BioReference agrees that it must comply with its plan of correction approved by the Department pursuant to this Consent Order. BioReference agrees that failure to comply with its plan of correction constitutes a violation of this Consent Order. BioReference agrees that the provisions of this Consent Order are in addition to its plan of correction. BioReference agrees that it must comply with this Consent Order and implement its plan of correction.
8. BioReference has consulted with its attorney prior to the execution of this Consent Order.
9. This Consent Order is a public document and it will be reported in accordance with state and federal law and regulation and consistent with Department policy. The Consent Order may be posted on the Department's website.
10. This Consent Order is effective on the date it is signed by the Commissioner of Public Health or her designee.

WITNESS WHEREOF, the parties hereto have caused this Consent Order to be executed by their respective officers and officials. Marc Grodman, M.D., represents that he is authorized to sign this Consent Order on behalf of BioReference.

BioReference

By: _____
Marc Grodman M.D.
President

On this 3rd day of November, 2014, before me, personally appeared Marc Grodman, M.D., President of BioReference, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained, by signing the name of the corporation by himself as President.

My Commission Expires: _____
(If Notary Public)

_____
~~Notary Public~~ [ ]
Commissioner of the Superior Court [X]

CONNECTICUT DEPARTMENT OF PUBLIC HEALTH

Signed on this 3rd day of November, 2014.

By: _____
Barbara Cass, R.N.
Section Chief
Facility Licensing and Investigations Section

EXHIBIT A

FLIS' Independent Consultant Guidelines

Relationship between Independent Consultant (IC) and DPH includes:

- An IC is utilized as a component of DPH's regulatory remedy process. An IC may be agreed upon as a part of a Consent Order between the institution and the Department when significant care and service issues are identified.
- The IC has a fiduciary or special relationship of trust, confidence and responsibility with the Department.
- The IC's responsibilities include:
  - Reporting to the Department issues and concerns regarding quality of care and services being provided by the institution.
  - Monitoring the institution's plan of correction to rectify deficiencies and violations of federal/state laws and regulations. Reports to Department positive and negative issues related to said oversight.
  - Assessing administration's ability to manage and the care/services being provided by staff.
  - Reporting in accordance with the Consent Agreement/Order to the Department of issues identified, plans to address noncompliance and remediation efforts of the institution.

Relationship between IC and the Institution:

- The IC maintains a professional and objective relationship with the institutional staff. The IC is a consultant, not an employee of the institution. The IC exercises independent judgment and initiative to determine how to fully address and complete her/his responsibilities. The institution does not direct or supervise the IC but must cooperate with and respond to requests of the IC related to her fulfilling her/his duties.
- The IC's responsibilities include:
  - Assessment of staff in carrying out their roles of administration, supervision and education.
  - Assessment of institution's compliance with federal/state laws and regulations.
  - Recommendations to institutional administration regarding staff performance.
  - Monitoring of care/services being provided.
  - Assists staff with plans of action to enhance care and services within the institution.
  - Recommendation of staff changes based on observations and regulatory issues.
  - Reports in accordance with the Consent Agreement/Order to the institution re: assessments, issues identified, and monitoring of plans of correction.
  - Promotes staff growth and accountability.
  - May present some inservices but primary function is to develop facility resources to function independently.
  - Educates staff regarding federal/state laws and regulations.