



Purpose: St. Luke’s Clinical Laboratory is a CLIA certified laboratory. Specimens referred for testing must be sent to CLIA-certified laboratories or laboratories meeting equivalent requirements as determined by CMS. Reference laboratories meeting quality performance indicators have proof of licensure by CLIA and/or one or more of the following accrediting organization/regulatory agency: CAP, AABB or FDA.

Selection and approval of a Reference Laboratory is the responsibility of St. Luke’s Clinical Laboratory management team and Cedar Valley Pathologists, under direction of the Laboratory Director.

Pathology approval is obtained for requests for specialized testing when the service is not available at an approved reference laboratory. It is prohibited to refer proficiency testing samples to another laboratory.

Process:

1. Documented process for evaluating and selecting reference laboratories can be found in meeting minutes for Laboratory Management and Medical Executive Committee, if deemed necessary by the Laboratory Director.

Expectations for testing services are evaluated using the following criteria:

- Laboratory HCFA certified for subspecialty
- Donor testing service FDA registered/inspected
- FDA approved testing kits used
- FDA testing algorithms used – exceptions reported to client
- Turnaround time for result reporting and billing information
- Change notification for testing and fee schedules
- Mode of sample delivery
- Mode of report delivery
- Frequency of testing
- Volume expectations
- Emergency needs
- Technical support
- Packaging/environment during transport
- Timeliness of billing

2. The following laboratories have been approved for referral testing:

Laboratory	Address/Phone/fax	URL address to view current licensure/accreditation certificates
Afirma	6000 Shoreline Court, Suite 300 South San Francisco, CA 94080 Ph: 1-844-464-5864 Fax: 1-650-243-6388	CLIA# 05D2014120 Afirma@ Thyroid Molecular Diagnostics
Ambry Genetics Corporation	7 ARGONAUT ALISO VIEJO, CA 92656 PH: 949-900-5500	CLIA: 05D0981414 CAP: 7154701 WWW.AMBRUGEN.COM
ARUP	500 Chipeta Way Salt Lake City, UT 84108-1221 PH: 1-800-522-2787	CLIA: 46D0523979 CAP: 4096301 https://www.aruplab.com/compliance/licensure-accreditations
AXIS Forensic Toxicology	5780 WEST 71 ST ST INDIANAPOLIS, IN 46278 PH: 1-317-715-0448	CAP LAP#6948901 CLIA#15D0647225 AMERICAN BOARD OF FORENSIC PATHOLOGY: L026 WWW.AXISFORTOX.COM
Ameritox	9930 West Highway 80 Midland, TX 79706	CAP LAP# 6348701 CLIA # 45D1005035



Laboratory	Address/Phone/fax	URL address to view current licensure/accreditation certificates
	Ph: 1-888-494-2165	www.Ameritox.com
Caris Life Sciences	4610 South 44 th Place Phoenix, Arizona 85040 Ph: 1-888-979-8669	CAP LAP# 7195577 CLIA# CMI03D1019490 www.carislifesciences.com
Esoterix, Inc. LabCorp	4301 Lost Hills Road Calabasas Hills, California 91301 Primary Phone: 800-444-9111 Primary Fax: 818-880-8541	CAP LAP# 2298301 CLIA# 05D0663070 https://specialtytesting.labcorp.com/about/certification-accreditation
Genomic Health	301 Penobscot Dr Redwood City, CA 94063 Ph: 1-866-662-6897	CAP LAP # 7186524 CLIA # 05D1018272 www.genomichealth.com
Interspace Biosciences	2515 Liberty Avenue Pittsburgh, PA 15222 Lab Ph: 844-405-9655 Client Services: 800-495-9885 Fax: 412-224-6425	CLIA# 39D1024654 Interpace Biosciences@.inc.(IDXG)
Invitae Corporation	1400 16 th Street San Francisco, CA 94103 Ph: 800-436-3037	CAP LAP# 8770489, AU-ID: 1703789 CLIA# 05D2040778 Licensing Invitae
Iowa Neonatal Metabolic Screening Program (INMSP) State Hygienic Laboratory	2220 S. Ankeny Blvd Ankeny, IA 50023-9093 Ph: 1-515-725-1600 Fax: 1-515-725-1642	CLIA# 16D0709302 www.uhl.uiowa.edu/aboutuhl/certifications.xml
Jones Regional Medical Center	1795 Hwy 64 E Anamosa, IA 52205 319-462-6131	CAP LAP# 6695701 CLIA# 16D0386387 Certificate not available on website, fax copy available
Karius Testing	975 Island Drive Redwood City, CA 94065 Ph:866-452-7487 Fax: 866-246-6567	CLIA #05D2121236 CAP #9497749 https://kariusdx.com/
LabCorp	8490 Upland Dr Englewood, CO 80112	CAP LAP#: 2177101 CLIA#:06D0680595 https://www.labcorp.com/node/85
LifeServe (Blood Bank)	431 East Locust Street Des Moines, IA 50309 Ph:800-287-4903	CLIA# 16D0383665 FDA# 1970355 AABB Licensure/Certification - LifeServe Blood Center
Linn County Health Department	501 13 th St. NW Cedar Rapids, IA 52405 Ph: 892-6000	CLIA# 16D0667607 Certificate not available on website, fax copy available.
Mayo Medical Laboratories	3050 Superior Dr NW Rochester, MN 55901 Ph: 1-800-533-1710	CLIA# 24D0404292 CAP LAP# 1808201 www.mayomedicallaboratories.com/customer-service/certificates.html



Laboratory	Address/Phone/fax	URL address to view current licensure/accreditation certificates
Medlabs	855 1 st Avenue, NE Cedar Rapids, IA 52402 Ph: 319-368-5650	CLIA# 16D0673649 CAP LAP# 412580101 www.medlabs.org
Mercy Medical Center Laboratory	701 10 th St SE Cedar Rapids, IA 52403 Ph: 319-398-6001	CLIA# 16D0386985 CAP LAP# 1770101
Natera	13011 McCallen Pass Building A Suite 100 Austin, TX 78753 201 Industrial Rd San Carlos, CA 94070	CLIA: 45D2093704 CAP: 8582677 CLIA: 05D1082992 CAP: 8737934 <u>Natera: A global leader in cell-free DNA testing</u>
NeoGenomics Laboratories	12701 Commonwealth Dr, Suite 9 Fort Meyers, FL 33913 PH: 1-866-776-5907	CLIA# 05D1021650 CAP LAP# 7181143 https://neogenomics.com/
National Medical Services INC	3701 Welsh Rd Willow Grove, PA 19090 PH: 1-866-522-2216	CLIA # 39D0197898 CAP LAP# 3030301 http://www.nmslabs.com/
Oxford Diagnostic Laboratories; Quest Diagnostics	5846 Distribution Dr Memphis, TN 38141 PH: 1-877-598-2522	CLIA: 44D2035207 NPI: 1114286523
Response Genetics	1640 Marengo St Los Angeles, CA 90033 Ph: 1-323-224-3900	CLIA# 05D1066073 CAP LAP# 7209131 www.responsegenetics.com
State Hygienic Laboratory	UI Research Park - Coralville Iowa City, IA 52242 Ph: 1-319-335-4500	CLIA# 16D0648109 www.uhl.uiowa.edu/aboutuhl/certifications.xml
University of Iowa Diagnostic Laboratories (UIDL)	200 Hawkins Drive Iowa City, IA 52242 Ph: 1-319-356-3527	CLIA# 16D0664625 CAP LAP# 1768801 FDA# 1972918 AABB# 006033 http://www.healthcare.uiowa.edu/pathology/site/certification/index.html
United States Drug Testing Lab	1700 S. Mt Prospect Rd. Des Plaines, IL 60018 Ph: 1-847-375-0770	CLIA# 14D0712964 CAP LAP# 3754202 www.usdtl.com/company/certifications.html
UnityPoint Health – Des Moines Pathology Laboratory	1212 Pleasant St Lower Level 3 Des Moines, IA 50309 Ph: 515-283-1791	CLIA# 16D0383397 CAP LAP# 1758001 www.pathologylab.org
Versiti	638 N 18th Street Milwaukee, WI 53233 Ph: 800-245-3117	CLIA#52D1009037 CAP#1780801 <u>Versiti - Accreditations & Licenses About Us</u>
Viracor Eurofins	1001 NW Technology Dr Lee's Summit, Missouri 64086 Ph: 1-800-305-5198	CLIA# 26D0983643 CAP LAP#7179041 WWW.VIROCOR-EUROFINS.COM



Laboratory	Address/Phone/fax	URL address to view current licensure/accreditation certificates
Yale University School of Medicine Department of Pathology Labs	310 Cedar Street LH 108 P.O. Box 208023 New Haven, CT 06520-8023 Ph: 877-925-3522	CLIA# 07D0098275 CAP# 1191007 <u>Department of Pathology < Pathology (yale.edu)</u>

3. Each reference lab report is reviewed at the time of resulting to monitor the quality of test results. It is the responsibility of the person entering and/or releasing results to review the report(s) prior to entry. Result entry is performed by Reference personnel and/or other qualified trained personnel, as appropriate. Refer to each specific procedure for instructions on reporting.
4. Essential elements of test results are reported in a manner to avoid alterations that could affect clinical interpretation.
5. Reports are retained based on what is outlined in the laboratory's retention policy. QP105_Records and Material Retention

References

College of American Pathologists, LAP, Laboratory General Checklist, GEN.41350, GEN.41430, GEN.41440, 8/17/16.

Related Documents

QP105_Records and Material Retention