

**Date: April 2022**

**Re: 2022 Annual Notification to Ordering Providers**

**Dear Valued Client:**

Thank you for allowing BioReference Laboratories (“BRLI”) to serve the health care needs of your patients. We are dedicated to providing you and your patients the highest quality service. We are equally committed to complying with all applicable federal and state health care laws, rules and regulations. This includes guidance published by the United States Department of Health and Human Services Office of Inspector General (the “OIG”) available at <https://oig.hhs.gov/fraud/docs/complianceguidance/thirdparty.pdf>.

The OIG recommends clinical laboratories send notices to ordering health care providers who use their services, at least once a year, to inform the recipients of the laboratory’s policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services. This Annual Notice is provided pursuant to that recommendation.

## **WHAT IS NEW FOR 2022**

**Celebrating our Scarlet Health® one-year anniversary.** This is an In-Home Diagnostic Service to Expand Digital Health Access. Scarlet Health® is BioReference’s on-demand, fully integrated digital solution that offers specimen collection at a convenient location of your patients’ choosing such as their home or workplace. To learn more, contact your account representative or email [hello@scarlethealth.com](mailto:hello@scarlethealth.com).

- **Scarlet will send your patient an email & a text with a link to schedule their appointment online.**
- **A Scarlet phlebotomist will go directly to your patient to collect their specimen.**
- **Lab test results will be sent to you the provider, electronically and made available to the patient via the secure HIPAA compliant patient portal.**

**The 4Kscore® Test:** The 4Kscore Test is a blood biomarker test for assessing the presence of aggressive prostate cancer. Formerly a Laboratory Developed Test (LDT), the 4Kscore Test was approved by the FDA on December 9<sup>th</sup>, 2021. When ordering this test, we require printed name and an inked signature and date from the physician or other authorized healthcare provider and the patient. Electronic or stamped signatures are not acceptable and will not be accepted.

## **ORDERING POLICIES:**

**Signed Requisitions:** There continues to be increased review efforts by payers verifying that the ordering provider has signed the requisitions for laboratory tests ordered. The requisition needs to be signed; the order can be electronically signed (non 4Kscore® Test) through an electronic medical record or ordering system; or documentation needs to be in the patient medical record at the treating provider site clearly indicating intent to order the test(s) and signed by the ordering provider e.g. MD. If submitting a paper requisition, we ask that you sign the hard copy requisition when ordering any testing submitted to our laboratory. This will mitigate the risk of BioReference Laboratories reaching out to your staff to retrieve evidence of the signed test order in your patient chart.

**Pre-Authorization for Laboratory Testing:** Insurance payers continue to increase oversight and restrict access by requiring pre-authorization for certain laboratory testing including but not limited to certain types of genetic carrier biomarkers and infectious disease panels. Any pre-authorization paperwork *must accompany* the laboratory requisition and specimen from the ordering provider. Please include the pre-authorization number on the test requisition. If we do not receive this at the time of the test order, it risks delay to your patient’s testing.

**ABN:** If a ‘non-covered’ diagnosis is used, the patient must be notified prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (“ABN”). The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. The signed, original ABN

must be attached to the original lab order prior to submission. In order for the laboratory to bill the patient, Medicare (and other payers) require that a patient sign an ABN informing them of the non-covered status of a test prior to the test being performed. Since we do not interact directly with patients, it is the responsibility of the ordering provider to be familiar with applicable NCD and LCD coverage rules, including ABN requirements, to ensure that informed medical necessity determinations, which take into consideration a patient's financial ability, are made for each patient and are supported by a signed order in the patient's medical record. Link: [www.medicare.gov](http://www.medicare.gov)

**Infectious Disease Testing:** BioReference cannot accept category A infectious substances as defined by IATA (Dangerous Goods Regulations BioReference Laboratories, Inc. 3.6.2.1.1 Definition – Infectious Substances), which include, but not limited to, specimens that may harbor variant Creutzfeldt-Jakob Disease (mad cow disease), variant Creutzfeldt-Jakob Disease, or tissue cultures of Mycobacterium tuberculosis. FFPE, fresh blood or bone marrow specimens, and body fluids are acceptable from patients with known tuberculosis. FYI: TB cases must be cultured within 24 hours. Specimens from other patients received in the same package will be considered potentially contaminated and handled in the same way, regardless of origination. If no options are available, specimens will be disposed as biohazardous waste after client notification. Please refer to IATA Dangerous Goods Regulations for a complete list of Category A Infectious Specimens: <https://www.iata.org/whatwedo/cargo/dgr/Documents/infectious-substance-classification-DGR56-en.pdf>

**Radioactive Specimens:** BioReference does not accept radioactive pathology samples, such as a prostate with radioactive seeds. There are specific shipping IAEA Shipping Standards that must be followed when sending to a qualified testing laboratory.

#### **STANDARDIZED POLICIES:**

**Coverage Standards:** As you know, Medicare and Medicaid only cover laboratory tests that are reasonable and necessary for the treatment or diagnosis of a patient. It is each provider's responsibility to order only those tests that are reasonable and necessary for each patient and that the ordering provider intends to use in the care of the patient. Medicare and its contractors have developed National and Local Coverage Determinations ("NCDs" and "LCDs") that provide guidelines regarding Medicare coverage of certain laboratory tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare, typically by reference to specific ICD-10 codes that are deemed to support coverage. You can find NCDs and LCDs online. Medicare reimbursement for each laboratory test can be found in the Medicare Clinical Laboratory Fee Schedule and the Medicare Physician Fee Schedule. Where an AMA CPT-defined Organ or Disease-Oriented Panel is ordered, that panel will be paid only if all components of the panel are medically necessary.

It is the policy of BRLI to only bill for panels and profiles when all the component tests are medically necessary, so the ordering provider agrees to only order panels or profiles when all component tests are medically necessary. Attached please find the American Medical Association (AMA) CPT-defined Organ or Disease-Oriented Panels: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3619CP.pdf>

**Test Ordering Options:** Regulations require that the performing laboratory have a written or electronic request for patient testing from an authorized person to order testing as defined by state law per the Clinical Laboratory Improvement Amendments ("CLIA"). The BRLI test requisition forms are designed to emphasize ordering provider choice and encourage ordering providers to order only those tests, which the ordering provider believes, are appropriate and medically necessary for the diagnosis or treatment of each patient. If BRLI receives a test order on a non-BRLI test requisition form or an incomplete BRLI test requisition form, processing of your test order may be delayed.

BRLI has three (3) options available by which an authorized provider may order BRLI testing. They include: 1) manual paper test requisitions; 2) online test ordering via our proprietary electronic ordering system InsightDX; and 3) EMR interface. Online ordering and EMR interface ordering are the more efficient methods of test ordering and help reduce potential human errors in the order creation and entry process. Our laboratory does

accept handwritten test requisitions but need them to be legible, complete and clear. Failure to provide a complete, clear and accurate test requisition may result in a delay in processing of a test order.

**Verbal Test Orders:** If an authorized person orders a test by telephone or wishes to add a test to an existing order, the laboratory must solicit a written or electronic authorization within thirty (30) days of the verbal request. If BRLI receives a verbal order, we will fax or email a confirmation form detailing the verbal order to the ordering provider and request that the provider sign and send the order form to BRLI.

**Billing Information:** BRLI test requisitions allow space to denote all information required for our Billing Department to submit claims to Medicare, Medicaid and all commercial, federal, and state funded insurance payers. The following information is necessary with any request for testing. Failure to provide the required information may result in BRLI contacting the provider's office via telephone, fax, or HIPAA secure email to obtain the missing billing information.

- **Patient's full, legal name as listed on their current health insurance policy**
- **Patient's mailing address, including city, state, and zip code**
- **Patient's date of birth**
- **Patient's biological gender at birth**
- **Patient's insurance company name, complete ID or policy number and complete group number, if applicable (if possible, a copy of the front and back of the patient's insurance card should be sent along with the test requisition)**
- **Ordering Provider or referring physician's name (must be authorized provider with BRLI)**
- **ICD-10 diagnosis code(s) to the highest level of specificity for each test ordered. ICD-10 diagnosis code(s) must be documented in the patient's medical record**
- **If using BRLI manual paper test requisitions, the signature of the ordering provider including provider credential**

Failure to provide a complete, clear and accurate test requisition may result in a delay in processing of a test order BRLI will not bill government or private payers for tests and services that are not medically reasonable and necessary, so the ordering provider agrees to only order tests that are medically necessary. Medicare, Medicaid and Commercial Payers audit BRLI from time to time and it may be necessary to contact the ordering provider to obtain medical records to support the test(s) ordered and the claim submitted by BRLI to the payer. BRLI encourages you to promptly comply with Payer requests for supporting patient medical documentation.

**Authorized Test Ordering:** Federal regulations require that a laboratory can only bill Medicare and Medicaid for testing ordered by a licensed physician or other non-physician practitioner ("NPP") authorized by state law to order laboratory tests. Our laboratory regularly screens all providers against Federal and State exclusion databases. If a provider is excluded, we immediately deactivate their ordering privileges while notifying the account sales representative. It is the Provider's responsibility to remedy the exclusion with the agency of record and we cannot accept any orders from that excluded or debarred provider unless and until the provider is removed from the excluded or debarred list. If your license has been revoked or suspended, it is your responsibility to notify our laboratory immediately. You represent and warrant that neither you, nor any employee, contractor or agent performing services on behalf of you has been excluded, debarred, suspended, proposed for debarment, or otherwise declared ineligible from any federal health care program or federal procurement or non-procurement program or convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7a. You further covenant that you will disclose any such debarment, suspension, exclusion, proposed debarment, or ineligibility to BRLI immediately upon discovery. Medicare requires that providers ordering laboratory testing on Medicare beneficiaries, must be registered in the Center for Medicare and Medicaid Services' ("CMS") Provider Enrollment, Chain and Ownership System ("PECOS"). It is BRLI's policy to only bill Medicare for laboratory testing ordered by a PECOS enrolled physician and performed by BRLI, per Medicare regulations. Additional information can be found at <https://pecos.cms.hhs.gov>

**Panels/Profiles:** BRLI offers you the opportunity to create a custom panel or profile. It is each ordering provider's responsibility to determine whether each test in a custom panel or profile is appropriate for a given patient. As the ordering provider, you have complete discretion concerning the tests you order for each of your patients. You may order tests individually or modify your custom panel(s) or profile(s) by adding or removing tests as appropriate

for any given patient, using the test requisition form. You may also modify your custom panel(s) or profile(s), if any, at any time by contacting your Account Executive. **Note: All profiles and panels are subject to medical quality review and oversight, and require approval prior to ordering.** It is the policy of BRLI to only bill for panels and profiles when all the component tests are medically necessary, so the ordering provider agrees to only order panels or profiles when all component tests are medically necessary.

**Diagnosis:** Ordering providers solely determine which tests are reasonable and necessary for their patients. BRLI solely relies on providers to make that determination and expects providers to provide accurate diagnostic information on their test requisitions. BRLI can provide a list of commonly used ICD-10 diagnosis codes but cannot recommend or suggest specific diagnosis codes to be used. Each ordering provider should document each patient's diagnosis in the patient's medical record and, by order of Section 4317 of the Balanced Budget Act of 1997, should include this diagnosis on any test requisition form submitted to BRLI through use of the correct ICD-10 diagnosis code(s) to the highest level of specificity.

Providers who do not provide required diagnosis information may be contacted by BRLI via telephone, fax or email. Per Medicare requirements, the physician or qualified NPP who orders the laboratory tests must maintain documentation of medical necessity in the beneficiary's medical record for the laboratory testing ordered. BRLI will not bill government or private payer for tests and services that are not medically reasonable and necessary, so the ordering provider agrees to only order tests that are medically necessary.

***The OIG takes the position that an ordering provider who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.***

**Ordering of Discretionary Tests:** The billing to a federally funded health care program, such as Medicare or Medicaid, of a test that is not reasonable and necessary for the diagnosis or treatment of a federal health care program beneficiary may be considered to be the submission of a false claim under the federal False Claims Act. The OIG has warned that physicians or other individuals authorized by law to order laboratory tests are subject to sanctions and other remedies under criminal, civil and administrative law if they knowingly cause the submission of a false claim to any federally funded health care program. If you determine that a test for a Medicare beneficiary is not reasonable and necessary, it is your responsibility to inform the beneficiary that Medicare will not pay for the test.

**Compliance:** We at BRLI are committed to compliance. Our Code of Conduct and Business Ethics identifies the values and obligations that all BRLI employees, officers, directors, consultants, and sales force must follow <https://www.bioreference.com/about/code-of-ethics/>. A full copy of our Code of Conduct and Business Ethics is available by written request directed to the BRLI Compliance Department at 481 Edward H. Ross Drive Elmwood Park, NJ 07407 or by calling our anonymous Compliance Hotline at 1-844-783-5587 or email at [ComplianceDepartment@bioreference.com](mailto:ComplianceDepartment@bioreference.com). If you have any questions or concerns about compliance, please call or write. Please also remember that federal law prohibits any person from offering or paying any remuneration, *i.e.*, anything of value, to induce the referral of tests that are covered by Medicare, Medicaid, or any other federal health care program. Any form of kickback, payment, or other remuneration that is intended to secure the referral of federal health care program testing business to BRLI is strictly prohibited and should be reported to the anonymous BRLI compliance hotline referenced-above.

**Patient Privacy (HIPAA):** Under the Health Insurance Portability and Accountability Act (HIPAA), BRLI is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at <https://www.bioreference.com/privacy/>.

**Clinical Consultant:** The laboratory's Director of Technical Operations and Medical Director are available to discuss appropriate testing and test ordering. If you have any questions, please do not hesitate to contact Customer Services at (800) 229-5227 Option 1 for assistance.

Please review this information with your staff as appropriate. We value your business and appreciate the opportunity to serve your laboratory needs in conjunction with these initiatives.

Best regards,

Robert J Rossi, Esquire  
SVP, Chief Compliance and Privacy Officer  
BioReference Laboratories

References:

<sup>1</sup> NCDs that apply to clinical laboratory testing: <https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx>

BRLI submits Medicare claims to the following MACs, for which the complete list of LCDs can be found at:

Novitas: NJ,MD,DC, PA: <https://www.novitassolutions.com/webcenter/portal/MedicareJL/LcdSearch>

Novitas: TX <https://www.novitas-solutions.com/webcenter/portal/MedicareJH/LcdSearch>

CGS Medicare (OH): <https://cgsmedicare.com>

FCSO (FL): [https://medicare.fcso.com/Coverage\\_Find\\_LCDs\\_and\\_NCDs/0488392.asp](https://medicare.fcso.com/Coverage_Find_LCDs_and_NCDs/0488392.asp)

Noridian (CA): <https://med.noridianmedicare.com/web/jeb>

NGS (NY): <https://www.ngsmedicare.com/web/ngs/medical-policies?lob=96664&state=97133&region=93623>

<sup>2</sup>The Medicare Clinical Laboratory Fee Schedule: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files>

<sup>3</sup> The Medicare Physician Fee Schedule: <https://www.cms.gov/apps/physician-fee-schedule/overview.aspx>