BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

MARCH 2020

Test Name	Test Code	Effective Date
Adrenal 21-Hydroxlase, AB	**3690**	**Immediately**

Due to changes made at our referral laboratory, testing methodology for **Adrenal 21-Hydroxlase, AB** has been updated from RIA to ELISA.

Test Name	Test Code	Effective Date
Alkaline Phosphatase, Isoenzymes	**0713**	**Immediately**

Due to changes made at our referral laboratory, reference ranges for **Alkaline Phosphatase, Isoenzymes** have been updated. Please refer to table below for changes.

	Previous Test Information	New Test Information
Reference Range	**Males** <1 month: 75-316 U/L 1-11 months: 82-383 U/L 1-3 years: 104-345 U/L 4-6 years: 93-309 U/L 7-9 years: 47-324 U/L 10-12 years: 91-476 U/L 13-15 years: 92-468 U/L 16-19 years: 48-230 U/L >=20 years: 40-115 U/L **Females** <1 month: 48-406 U/L 1-11 months: 124-341 U/L 1-3 years: 108-317 U/L 4-6 years: 96-297 U/L 7-9 years: 184-415 U/L 10-12 years: 104-471 U/L 13-15 years: 41-244 U/L 16-19 years: 47-176 U/L 20-49 years: 33-115 U/L >=50 years: 33-130 U/L	**Males** 0-6 days 46-245 U/L 7-14 days 69-306 U/L 15 days - <1 month 113-412 U/L 1-5 months 104-450 U/L 6-11 months 100-334 U/L 1-9 years 117-311 U/L 10 years 128-396 U/L 11 years 125-428 U/L 12 years 123-426 U/L 13 years 100-417 U/L 14 years 78-326 U/L 15 years 65-278 U/L 16 years 56-234 U/L 17-19 years 46-169 U/L 20-49 years 36-130 U/L >49 years 35-144 U/L **Females** 0-6 days 46-245 U/L 7-14 days 69-306 U/L 15 days - <1 month 113-412 U/L 1-5 months 104-450 U/L 6-11 months 100-334 U/L 1-9 years 117-311 U/L 10 years 128-396 U/L 11 years 100-429 U/L 12 years 69-296 U/L 13 years 58-258 U/L 14 years 51-179 U/L 15 years 45-150 U/L 16 years 41-140 U/L 17-19 years 36-128 U/L 20-49 years 31-125 U/L >49 years 37-153 U/L

481 Edward H Ross Drive | Elmwood Park NJ 07407 | tel 800 229 5227 | fax 201 791 1941 | www.bioreference.com

BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

MARCH 2020

Test Name	Test Code	Effective Date
Beta-Glucosidase, Leukocytes	**6262**	**Immediately**

Due to changes made at our referral laboratory, test information for **Beta-Glucosidase, Leukocytes** has been updated. Please refer to table below for changes.

	Previous Test Information	New Test Information
Methodology	Flourometric	Flow Injection Analysis-Tandem Mass Spectrometry
Reference Range	≥ 8.7 nmoL/h/mg Prot	≥ 3.53 nmoL/hour/mg protein
Physician Attestation of Informed Consent	Not required	This germline genetic test requires physician attestation that patient consent has been received if ordering medical facility is located in AK, DE, FL, GA, IA, MA, MN, NV, NJ, NY, OR, SD or VT or test is performed in MA.

Galectin-3	**B156**	**Immediately**

Due to changes made at our referral laboratory, **Serum** is now the only accepted specimen type for **Galectin-3.**

GenArray™ Molecular Karyotyping	**5306**	**April 1**

Effective April 1, 2020, **GenArray™ Molecular Karyotyping by array comparative genomic hybridization** (array CGH, test code 5306) will be discontinued. This test, which can detect unbalanced gains and losses of genomic DNA in hematologic neoplasia, has been used as in the past as a supplement to conventional cytogenetic karyotypic analysis. The advent and growth of NGS (Next Generation Sequencing) testing has generally supplanted the utility of array CGH, typically provides more actionable information, and is included in the NCCN guidelines.

Prenatal Targeted Array	**A583**	**March 2**
Prenatal Targeted Array (Reflex from FISH)	**B222**	
Prenatal Targeted Array (Reflex from chromosomes)	**A592**	
Prenatal Targeted Array	**A583**	

The laboratory is switching platforms from Agilent 60k to Affymetrix CytoScan HD for **Prenatal Targeted Array** testing.

The Affymetrix ("Affy") array is more tolerant of suboptimal DNA which is more likely to be found in uncultured (direct) prenatal amniocentesis and CVS specimens. We expect this to reduce the number of samples requiring culture and result in improved turnaround times.

The legacy platform provided 100 targeted regions to assess for microdeletions and microduplications, whereas the new Affy array targets approximately 150 regions.. The Affy array has many more probes for copy number, and also more SNP probes for detection of regions of homozygosity (ROH), but we will be analyzing the non-targeted region at a much lower resolution in order to decrease the number of variants of unknown significance (VUS). We will still be reporting ROH only on chromosomes 6, 7, 11, 14, 15, and 20 as we have been doing on our prenatal targeted array since those are the chromosomes where there are imprinted regions/genes and, therefore, where uniparental disomy (UPD) may be involved.

Note that the Affy technology is not array comparative genomic hybridization based, therefore we will no longer refer to this as an aCGH array. It is appropriate to use the more general term "chromosomal microarray" or "CMA".

	Previous Test Information	New Test Information
Methodology	Agilent 60k CGH array	Affymetrix CytoScan HD array with intentionally reduced detection in the non-targeted regions
Reference Range	At least 3 probes with increased probe density in clinically relevant regions and sparse probe density in the rest of the genome	At least 25kb deletion and 50kb duplications in targeted regions; at least 1 Mb deletions and 2 Mb duplications in non-targeted regions

481 Edward H Ross Drive | Elmwood Park NJ 07407 | tel 800 229 5227 | fax 201 791 1941 | www.bioreference.com

BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

MARCH 2020

Test Name	Test Code	Effective Date
Prenatal Whole Genome Chromosomal Microarray	**A591**	**March 2**

The laboratory is switching platforms from Agilent 180k to Affymetrix CytoScan HD for **Prenatal Whole Genome Chromosomal Microarray**. The Affymetrix ("Affy") array is more tolerant of suboptimal DNA such as is found in amniotic fluid, CVS and products of conception (POC) specimens. We expect this to permit us to optimize our chances of getting an array result without having to perform cell culture first for prenatal or POC specimens, thereby eventually reducing turnaround time. Furthermore, for low DNA concentration specimens, this array will maximize the chance at achieving a result.

The Affy array has many more probes for copy number (1.9 million vs 114,000) and also more SNP probes (750,000 vs 40,000) for detection of regions of homozygosity (ROH). We will report deletions that are at least 25kb and include at least 25 probes, and duplications that are at least 50 kb and include at least 50 probes. Similar to what we have been doing, autosomal ROH will be reported when there is at least one region of homozygosty of >10 Mb or when there are two regions that are at least 8 Mb. Only ROH calls >5 Mb are included in the report.

Note that the Affy technology is not array comparative genomic hybridization based, so we will no longer refer to this as an aCGH array. It is appropriate to use the more general term "chromosomal microarray" or "CMA". Also, this is the same array and reporting parameters that we will be using for postnatal specimens. Since more than 50% of our postnatal specimens are buccals which provide low quality, low concentration DNA, we expect the Affy array to handle this specimen type better than the Agilent array resulting in fewer repeats and eventually better TAT on our postnatal samples as well.

	Previous Test Information	New Test Information
Methodology	Agilent 180k CGH array	Affymetrix CytoScan HD array
Reference Range	At least 25kb deletion and 50kb duplications	At least 25kb including at least 25 probes for deletions and 50kb including at least 50 probes for duplications

REGIONAL UPDATE - INR **1112** **February 13**

Due to reagent changes, the reference range for Normal Non-Medicated Patients for INR has been updated when performed at our Elmwood Park, NJ laboratory location.

	Previous Test Information	New Test Information
Reference Range	0.82-1.09	0.80-1.07

REMINDER - 4Kscore Test **J148, J264 and K135** **Immediately**

The final Local Coverage Determination (LCD) from the Medicare MAC for the 4Kscore® Test, Novitas, is now effective. Please be reminded that the LCD includes defined coverage criteria from Medicare, including required documentation of Shared Decision Making prior to ordering the 4Kscore Test. Full text of the final LCD can be found at http://bit.ly/4KscoreLCD.

The 4Kscore Test requisition form was modified to support the updated coverage criteria and is now the only requisition form that can be used to place an order for the 4Kscore Test. If documentation is **INCOMPLETE**, results may be delayed. In cases where complete documentation is not received by the lab following communication with your office, the test may be cancelled after a holding period.

Summary of Changes:

1. BOTH provider and patient signatures, legible names, and dates attesting to Shared Decision Making are required when ordering the 4Kscore Test, and must be sent to the laboratory.
2. ALL questions in the Prostate Cancer Risk Evaluation section of the requisition form MUST BE COMPLETED.
3. A COPY of the completed test requisition with Shared Decision Making should be retained in the patient's medical record.

Your Account Executive can provide you with additional details and information as needed. If you have any further questions, please call our 4Kscore Customer Service team at **833-4KSCORE (833-457-2673)** or visit our website at https://www.4kscore.com/.

481 Edward H Ross Drive | Elmwood Park NJ 07407 | tel 800 229 5227 | fax 201 791 1941 | www.bioreference.com

BioReference LABORATORIES | genpath

OPKO Health Companies

Client Update

MARCH 2020

Test Name	Test Code	Effective Date
REMINDER - Comprehensive Respiratory Panel	**L740**	**Immediately**

Please be reminded that **The Comprehensive Respiratory Panel** is now available for testing. The panel provides comprehensive testing for upper respiratory infections, and simultaneously detects 17 viral and 4 bacterial infectious agents that present with similar flu-like symptoms.

The Comprehensive Respiratory Panel does not include testing for the detection of the 2019 Novel Coronavirus (COVID-19). It does test for several other Coronaviridae (229E, HKU1, NL63 and OC43). BioReference is working expeditiously to identify the best path forward to develop and offer a test that will yield high quality and accurate results. We will provide an update in the near future regarding the date testing will become available at our laboratory in accordance with CDC and FDA Guidance.

	New Test Information
Primary Container	Viral Swab - Media Male And Flu Naso (Item # 510).
Turn Around Time*	2 Days
Transportation Temp	Refrigerate
Stability	3 Days
Methodology	Polymerase Chain Reaction
Collection Instructions	Nasopharyngeal Swab (NPS) collected according to standard technique and immediately placed in 1-3 mL of Viral transport media.
Profile Components	**Viral:** Adenovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H3, Influenza A/H1-2009, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus. **Bacterial:** Bordetella parapertussis, Bordetella pertussis, Chlamydia pneumonia, Mycoplasma pneumoniae
CPT Code(s)**	87486x1, 87581x1, 87633x1, 87798x1
Clinical Utility	Assess for various viral and bacterial infectious agents associated with symptomatic upper respiratory infections.

NOTE: When ordering tests, providers should only order tests that are medically necessary for the diagnosis or treatment of a patient, generally not for screening. Only a few screening tests are covered by most government and third party payers for certain conditions at specific intervals.

NOTES:

Client updates are also available to be received via email instead of fax. To subscribe to receive client updates via email, please visit http://bioreferencelabs.bioreference.com/go-green

* TAT is based upon receipt of the specimen at the laboratory.

**CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

481 Edward H Ross Drive | Elmwood Park NJ 07407 | tel 800 229 5227 | fax 201 791 1941 | www.bioreference.com