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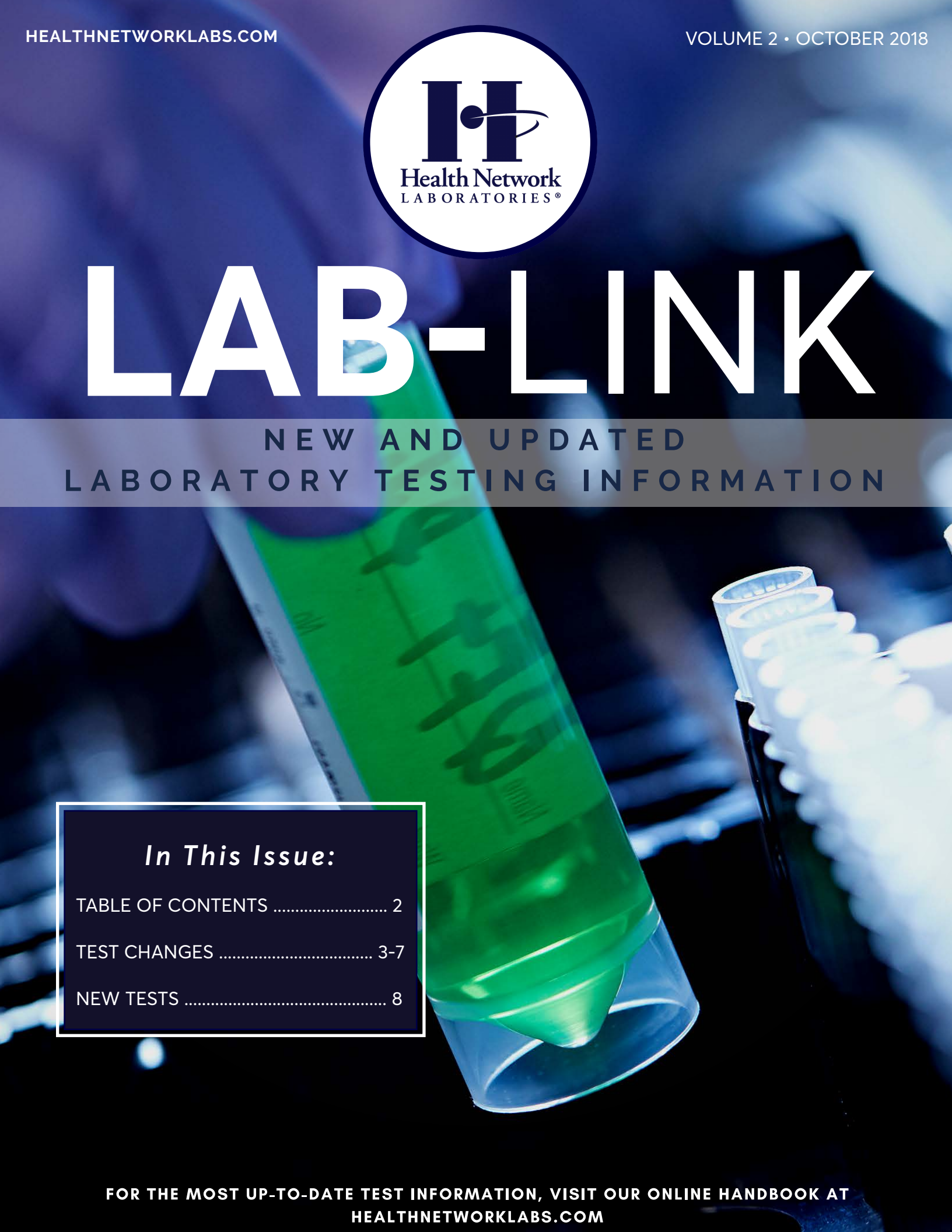
Health Network LABORATORIES®

LAB-LINK

NEW AND UPDATED LABORATORY TESTING INFORMATION



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FOR THE MOST UP-TO-DATE TEST INFORMATION, VISIT OUR ONLINE HANDBOOK AT HEALTHNETWORKLABS.COM

TEST CHANGES

CRITICAL VALUE CHANGE: *Lipase, Serum (LIPS)*	
Description of Change:	Health Network Laboratories (HNL) will be adding a critical value for the test, "Lipase, Serum" (LIPS).
Effective Date:	**09/27/2018**
Critical Value:	**> 720 U/L**
Methodology:	Rate
Testing Schedule:	Routine daily, STAT testing available
Report Availability:	1 day
Specimen Requirements:	Minimum Volume: ♦ 1 mL serum or plasma Container: ♦ Gold top tube, serum separator OR Light Green top tube, plasma separator
Reference Range:	80-360 U/L ACL–Pocono: 11-82 U/L
Clinical Utility:	Used in evaluating disorders of the pancreas.
Special Instructions:	All existing requests for a critical value modification will remain in effect. To request a critical value modification or to change an existing critical value modification, please contact: **Sales Support department at** 484-425-5070

TEST CHANGES

BCR/ABL By Reverse Transcription Polymerase Chain Reaction (BCABL)	
Description of Change:	The minimum number of drawn tubes is increasing from two lavender top tubes to three lavender top tubes.
Effective Date:	**10/16/2018**
Methodology:	Quantitative Reverse Transcription Polymerase Chain Reaction
Testing Schedule:	Routine, Monday - Friday, no holidays
Report Availability:	7 days
Specimen Requirements	Minimum Volume: ♦ 6 mL whole blood **Container:** ♦ **3 Lavender top tubes, EDTA** Collection: ♦ Collect Monday - Friday only before 1400, no holidays. ♦ Specimens must arrive in the core Laboratory at Roble Road by 1600.
Reference Range:	See Patient Report
Clinical Utility:	The use of this assay helps physicians to determine whether a major molecular response (MMR) has been achieved in Chronic Myeloid Leukemia (CML) patients, indicating progression-free survival. Increases in BCR-ABL/ABL %IS may indicate a loss of response, or resistance to therapy.
Special Instructions:	Store as whole blood in original tube refrigerated. Submit specimen with a completed Hematopathology Requisition (HNL-05) Form. Clinical history, diagnosis, and specimen type are required. Form can be requested by contacting the Customer Care Department 1-877-402-4221.

For additional information, please contact Allyssa Staboleski, Manager, Molecular Diagnostics at 877-402-4221.

TEST CHANGES

HBV Viral Load, PCR (HBVLD)	
Description of Change:	Health Network Laboratories will be modifying the reports for HBV viral loads. The reference range will change from 'Not Detected' to the lower limit of quantitation. An interpretation field will also be included in the report. The reference range for the interpretation field is 'Not Detected.'
Effective Date:	**10/22/2018**
Includes:	Quantitation of Hepatitis B viral load in human plasma or serum.
Methodology:	Real Time Polymerase Chain Reaction (PCR)
Testing Schedule:	Routine, 1 time per week
Report Availability:	7 days
Specimen Requirements	Minimum Volume: ♦ 1 mL plasma OR 1 mL serum Container: ♦ 2 Lavender top tubes, EDTA OR 2 Gold top tubes, serum separator
Reference Range:	**Not Detected** **Level of Quantitation : 10 IU/mL** **Assay Range: 10 - 1,000,000,000 IU/mL**
Clinical Utility:	Nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) in human serum or plasma. Used as an aid in the management of patients with chronic HBV infection undergoing antiviral therapy. The test can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment.
Special Instructions:	For Lavender top, EDTA tubes: Centrifuge specimen for 20 minutes at 800 - 1600 x g (3000 rpm) within 24 hours of collection. Following centrifugation, aseptically transfer all plasma to plastic screw-cap aliquot tube. Refrigerate. For Gold top tubes, serum separator: Centrifuge specimen for 20 minutes at 800 - 1600 x g (3000 rpm) within 24 hours of collection. Do not aliquot. Refrigerate

For additional information, please contact Allyssa Staboleski, Manager, Molecular Diagnostics at 877-402-4221.

TEST CHANGES

HCV Viral Load, RT-PCR (HCVLD)

Description of Change:	Health Network Laboratories will be modifying the reports for HCV viral loads. The reference range will change from 'Not Detected' to the lower limit of quantitation. An interpretation field will also be included in the report. The reference range for the interpretation field is 'Not Detected.'
Effective Date:	**10/22/2018**
Methodology:	Real Time Reverse Transcription Polymerase Chain Reaction
Testing Schedule:	Routine, 2 times per week
Report Availability:	4 - 7 days
Specimen Requirements	Minimum Volume: ♦ 4 mL plasma OR ♦ 4 mL serum Container: ♦ 2 White top tubes, EDTA PPT OR ♦ 2 Lavender top tubes, EDTA OR ♦ 2 Gold top tube, serum separator
Reference Range:	**Not Detected** **Level of Quantitation: 15 IU/mL** **Assay Range: 15 - 100,000,000 IU/mL**
Clinical Utility:	This test utilizes a dual-probe approach to viral load testing, increasing the ability to detect HCV genotypes 1-6 to a lower limit of quantitation of 15 IU/ml. The assay measures HCV RNA levels of established Hepatitis C infected individuals at baseline and during treatment. It can be used to predict sustained virologic response (SVR) to demonstrate efficacy of the antiviral treatment.
Special Instructions:	Freshly drawn specimens may be stored at 2° to 25°C for up to 24 hours prior to centrifugation. For White top, EDTA tubes: Centrifuge specimen for 20 minutes at 800-1600 x g (3000 rpm) within 24 hours of collection. Do not aliquot. Refrigerate. For Lavender top, EDTA tubes: Centrifuge specimen for 20 minutes at 800-1600 x g (3000 rpm) within 24 hours of collection. Aseptically transfer plasma to plastic aliquot tube. Refrigerate. For Gold top, serum tubes: Centrifuge specimen for 20 minutes at 800-1600 x g (3000 rpm) within 24 hours of collection. Do not aliquot. Refrigerate.

For additional information, please contact Allyssa Staboleski, Manager, Molecular Diagnostics at 877-402-4221.

TEST CHANGES

HCV Genotype with HCV Viral Load (HEPCG)

Description of Change:	Health Network Laboratories will be modifying the reports for HCV viral loads. The reference range will change from 'Not Detected' to the lower limit of quantitation. An interpretation field will also be included in the report. The reference range for the interpretation field is 'Not Detected.'
Effective Date:	**10/22/2018**
Includes:	♦ Hepatitis C Viral Load (IU/mL) ♦ Hepatitis C Genotype ♦ Additional CPT codes may apply
Methodology:	HCV Viral Load: Reverse Transcription Polymerase Chain Reaction (RT-PCR) HCV Genotype: Reverse Transcription Polymerase Chain Reaction (RT-PCR) followed by solid phase electrochemical methodology
Testing Schedule:	Routine, Monday - Friday, no holidays
Report Availability:	4 - 6 Days
Specimen Requirements	Minimum Volume: ♦ 3 mL EDTA plasma Container: ♦ 3 White Top Tubes, EDTA PPT OR ♦ 3 Lavender Top Tubes, EDTA
Reference Range:	**HCV Viral Load: Not Detected** **HCV Viral Load: Not Detected** **HCV Genotyping can only be performed on specimens with viral loads greater than or equal to 500 IU/mL.**
Clinical Utility:	Hepatitis C Virus is now a curable disease and advances in HCV therapy have resulted in steadily higher cure rates. Before treatment for HCV can be commenced however, it is necessary to genotype the virus as different genotypes require different types and durations of treatment.
Special Instructions:	Freshly drawn specimens may be stored at 2 - 8°C for up to 24 hours prior to centrifugation. For White top, EDTA tubes: Centrifuge specimen for 20 minutes at 800-1600 x g (3000rpm) within 24 hours of collection. Do not aliquot. Refrigerate. For Lavender top, EDTA tubes: Centrifuge specimen for 20 minutes at 800-1600 x g (3000rpm) within 24 hours of collection. Transfer plasma to plastic aliquot tube. Refrigerate.

For additional information, please contact Allyssa Staboleski, Manager, Molecular Diagnostics at 877-402-4221.

NEW TEST

HCV Genotype Only (HEPGN)

Effective Date:	**08/28/2018**
Methodology:	Reverse Transcription Polymerase Chain Reaction (RT-PCR) followed by solid phase electrochemical methodology.
Testing Schedule:	Routine, Monday - Friday, no Holidays
Report Availability:	4 - 6 Days
Specimen Requirements:	(Minimum Volume): ♦ 2mL EDTA plasma (Container): ♦ 2 White Top Tubes, EDTA PPT
Special Instructions:	Freshly drawn specimens may be stored at 2 - 8°C for up to 24 hours prior to centrifugation. Centrifuge specimen for 20 minutes at 800 - 1600 x g (3000rpm) within 24 hours of collection. Do not aliquot. Refrigerate.
Clinical Utility:	Hepatitis C Virus is now a curable disease. Advances in HCV therapy have resulted in steadily higher cure rates. Before treatment for HCV can start, it is recommended to genotype the virus as different genotypes require different types and durations of treatment. The HCV Genotype Only Test (HEPGN) is intended to be ordered for known HCV positive patients with a minimum viral load of 500 IU/mL. If patient's HCV viral load is unknown, refer to HCV Genotype with HCV Viral Load test (HEPCG).

For additional information, please contact Allyssa Staboleski, Manager, Molecular Diagnostics at 877-402-4221.