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Health Network LABORATORIES®

LAB-LINK

NEW AND UPDATED LABORATORY TESTING INFORMATION

In This Issue:

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TEST CHANGES

CBC, No Differential (CBC)

Description of Change:	Reference range update for select parameters within a CBC.
Effective Date:	**06/12/2019** *Note: Hemoglobin (HGB) and Hematocrit (HCT) change occurred October 30, 2018.*
Includes:	• White Blood Cell Count (WBC) • Red Blood (RBC) • Hemoglobin (HGB) • Hematocrit (HCT) • Mean Corpuscular Volume (MCV) • Mean Corpuscular Hemoglobin (MCH) • Mean Corpuscular Hemoglobin Concentration (MCHC) • Red Blood Cell Distribution Width (RDW) • Platelet count (PTL)
Methodology:	Automated Analyzer
Testing Schedule:	Routine daily, STAT testing available.
Report Availability:	1 day
Specimen Requirements:	Minimum Volume: 1.5 mL whole blood or 300-500 µL in BD Microtainer™ tube. Container: Lavender top tube, EDTA.
Clinical Utility	Used in the evaluation of infection, anemia, and other hematological disorders.
Reference Range:	**UPDATED HEMATOLOGY REFERENCE RANGES**

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
WBC thou/cmm	0-14 DAYS	8.0	15.4	0-14 DAYS	8.2	14.6
	15-30 DAYS	7.8	15.9	15-30 DAYS	8.4	14.4
	31-60 DAYS	8.1	15.0	31-60 DAYS	7.1	14.7
	61-180 DAYS	6.5	13.3	61-180 DAYS	6.0	13.3
	0.5-<2 YEARS	6.0	13.5	0.5-<2 YEARS	6.5	13.0
	2-<3 YEARS	5.1	13.4	2-<3 YEARS	4.9	13.2
	3-5 YEARS	4.4	12.9	3-5 YEARS	4.4	12.9
	6-17 YEARS	3.8	10.4	6-17 YEARS	3.8	10.4
	≥18 YEARS	4.0	10.5	≥18 YEARS	4.0	10.0

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TEST CHANGES *(cont.)*

Reference Range *(cont.)*:

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
RBC mill/cmm	0-14 DAYS	4.10	5.55	0-14 DAYS	4.12	5.74
	15-30 DAYS	3.16	4.63	15-30 DAYS	3.32	4.80
	31-60 DAYS	3.02	4.22	31-60 DAYS	2.93	3.87
	61-180 DAYS	3.43	4.80	61-180 DAYS	3.45	4.75
	0.5-<2 YEARS	4.03	5.07	0.5-<2 YEARS	3.97	5.01
	2-<3 YEARS	3.89	4.97	2-<3 YEARS	3.84	4.92
	3-5 YEARS	4.00	5.10	3-5 YEARS	4.00	5.10
	6-10 YEARS	4.10	5.20	6-10 YEARS	4.10	5.20
	11-14 YEARS	4.20	5.30	11-14 YEARS	4.10	5.10
	15-17 YEARS	4.30	5.70	15-17 YEARS	3.80	5.00
	≥18 YEARS	4.00	5.40	≥18 YEARS	3.70	4.70

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
HGB g/dL	0-14 DAYS	13.9	19.1	0-14 DAYS	13.4	20.0
	15-30 DAYS	10.0	15.3	15-30 DAYS	10.8	14.6
	31-60 DAYS	8.9	12.7	31-60 DAYS	9.2	11.4
	61-180 DAYS	9.6	12.4	61-180 DAYS	9.9	12.4
	0.5-<2 YEARS	10.1	12.5	0.5-<2 YEARS	10.2	12.7
	2-<3 YEARS	10.2	12.7	2-<3 YEARS	10.2	12.7
	3-5 YEARS	11.4	14.3	3-5 YEARS	11.4	14.3
	6-8 YEARS	11.5	14.3	6-8 YEARS	11.5	14.3
	9-10 YEARS	11.8	14.7	9-10 YEARS	11.8	14.7
	11-14 YEARS	12.4	15.7	11-14 YEARS	11.9	14.8
	15-17 YEARS	13.3	16.9	15-17 YEARS	11.9	14.8
	≥18 YEARS	12.5	17.0	≥18 YEARS	11.5	14.5

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
HCT %	0-14 DAYS	39.8	53.6	0-14 DAYS	39.6	57.2
	15-30 DAYS	30.5	45.0	15-30 DAYS	32.0	44.5
	31-60 DAYS	26.8	37.5	31-60 DAYS	27.7	35.1
	61-180 DAYS	28.6	37.2	61-180 DAYS	29.5	37.1
	0.5-<2 YEARS	30.8	37.8	0.5-<2 YEARS	30.9	37.9
	2-<3 YEARS	31.0	37.7	2-<3 YEARS	31.2	37.8
	3-5 YEARS	34.0	42.0	3-5 YEARS	34.0	42.0
	6-7 YEARS	34.0	42.0	6-7 YEARS	34.0	42.0
	8-11 YEARS	35.0	43.0	8-11 YEARS	35.0	43.0
	12-15 YEARS	38.0	47.0	12-15 YEARS	35.0	43.0
	16-17 YEARS	40.0	50.0	16-17 YEARS	35.0	43.0
	≥18 YEARS	37.0	48.0	≥18 YEARS	35.0	43.0

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TEST CHANGES *(cont.)*

Reference Range *(cont.)*:

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
MCV fL	0-14 DAYS	91	103	0-14 DAYS	93	106
	15-30 DAYS	89	100	15-30 DAYS	90	103
	31-60 DAYS	84	94	31-60 DAYS	83	96
	61-180 DAYS	74	88	61-180 DAYS	75	88
	0.5-<2 YEARS	70	82	0.5-<2 YEARS	71	83
	2-<3 YEARS	71	84	2-<3 YEARS	72	85
	3-5 YEARS	77	90	3-5 YEARS	77	90
	6-11 YEARS	78	91	6-11 YEARS	78	91
	12-14 YEARS	80	93	12-14 YEARS	80	93
	15-17 YEARS	83	98	15-17 YEARS	83	98
	≥18 YEARS	80	100	≥18 YEARS	80	100

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
MCH pg	0-14 DAYS	31.3	35.6	0-14 DAYS	31.1	35.9
	15-30 DAYS	29.9	34.1	15-30 DAYS	30.4	35.3
	31-60 DAYS	27.8	32.0	31-60 DAYS	28.0	32.5
	61-180 DAYS	24.4	28.9	61-180 DAYS	24.4	29.5
	0.5-<2 YEARS	22.7	27.2	0.5-<2 YEARS	23.2	27.5
	2-<3 YEARS	23.7	28.3	2-<3 YEARS	23.7	28.6
	3-5 YEARS	26.1	30.7	3-5 YEARS	26.1	30.7
	6-15 YEARS	26.3	31.7	6-15 YEARS	26.3	31.7
	16-17 YEARS	27.6	33.3	16-17 YEARS	27.6	33.3
	≥18 YEARS	27.0	36.0	≥18 YEARS	26.0	34.0

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
MCHC g/dL	0-14 DAYS	33.0	35.7	0-14 DAYS	33.4	35.4
	15-30 DAYS	32.7	35.1	15-30 DAYS	33.2	35.0
	31-60 DAYS	32.3	34.8	31-60 DAYS	32.5	34.9
	61-180 DAYS	31.9	34.4	61-180 DAYS	32.1	34.4
	0.5-<2 YEARS	31.6	34.4	0.5-<2 YEARS	31.9	34.2
	2-<3 YEARS	32.0	34.7	2-<3 YEARS	31.8	34.6
	3-5 YEARS	32.4	34.9	3-5 YEARS	32.4	34.9
	6-17 YEARS	32.5	35.2	6-17 YEARS	32.5	35.2
	≥18 YEARS	32.0	37.0	≥18 YEARS	32.0	37.0

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TEST CHANGES *(cont.)*

Reference Range *(cont.)*:

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
RDW %	0-14 DAYS	14.8	17.0	0-14 DAYS	14.6	17.3
	15-30 DAYS	14.3	16.8	15-30 DAYS	14.4	16.2
	31-60 DAYS	13.8	16.1	31-60 DAYS	13.6	15.8
	61-180 DAYS	12.4	15.3	61-180 DAYS	12.2	14.3
	0.5-<2 YEARS	12.9	15.6	0.5-<2 YEARS	12.7	15.1
	2-<3 YEARS	12.5	14.9	2-<3 YEARS	12.4	14.9
	3-5 YEARS	11.3	13.4	3-5 YEARS	11.3	13.4
	6-17 YEARS	11.4	13.5	6-17 YEARS	11.4	13.5
	≥18 YEARS	12.0	16.0	≥18 YEARS	12.0	16.0

	MALE			FEMALE		
ANALYTE	AGE	LOWER	UPPER	AGE	LOWER	UPPER
PTL thou/cmm	0-14 DAYS	218	419	0-14 DAYS	144	449
	15-30 DAYS	248	586	15-30 DAYS	279	571
	31-60 DAYS	229	562	31-60 DAYS	331	597
	61-180 DAYS	244	529	61-180 DAYS	247	580
	0.5-<2 YEARS	206	445	0.5-<2 YEARS	214	459
	2-<3 YEARS	202	403	2-<3 YEARS	189	394
	3-5 YEARS	187	445	3-5 YEARS	187	445
	6-9 YEARS	187	400	6-9 YEARS	187	400
	10-13 YEARS	177	381	10-13 YEARS	177	381
	14-17 YEARS	139	320	14-17 YEARS	158	362
	≥18 YEARS	140	350	≥18 YEARS	140	350

For additional information, please contact Diane Raber, Technical Specialist, Automation at 877-402-4221.

NEW TEST

NEW TEST CODE

C. Diff Toxin Gene with Reflex (CDRFX)

DESCRIPTION OF CHANGE:

Health Network Laboratories currently uses a *C. difficile* polymerase chain reaction (PCR) test to diagnose suspected *C. difficile* colitis. This test, while very sensitive, does not test for active toxin production. The PCR assay detects the gene that codes for toxin production. In order to better distinguish between active infection and asymptomatic colonization HNL is transitioning to a multistep testing algorithm. The *C. difficile* PCR assay (C DIFF PCR) will be performed initially and if positive reflexed to *C. difficile* toxin testing (C DIFF TOXIN EIA). This new protocol is in alignment with recent *C. difficile* clinical practice guideline updates and will begin on June 3, 2019.

THE TEST WILL INTERPRET AS FOLLOWS:

If the specimen is C DIFF Tox Gene, PCR negative (not detected), it is NEGATIVE for *C. difficile*.

If the specimen is C DIFF Tox Gene, PCR positive (detected) and C DIFF TOXIN negative, this is compatible with COLONIZATION; treatment is rarely warranted but the patient should remain on contact isolation if hospitalized.

If the specimen is C DIFF Tox Gene, PCR Positive and C DIFF TOXIN positive, this is compatible with ACTIVE INFECTION with *C. difficile*. This patient warrants treatment and should be in contact isolation if hospitalized.

Please see attached testing algorithm on page 9 for more details.

The test code CDPCR (*CLOSTRIDIUM DIFFICILE* TOXIN BY DNA PROBE, STOOL) will be inactivated and replaced by CDRFX (C DIFF TOX GENE/RFX).

Both the CSPCR (Comprehensive Stool PCR) and the BSPCR (Bacterial Stool PCR) assays will also reflex to the C DIFF TOXIN EIA if *C. difficile* is detected.

Effective Date:	**06/03/2019**
CPT Codes:	CPT - C diff PCR 87493 CPT – C diff TOX/GDH EIA - 87324 (Toxin assay), 87449 (GDH)
Methodology:	Initial testing DNA PCR Reflex testing EIA
Testing Schedule:	Routine, daily
Report Availability:	1 day

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NEW TEST *(cont.)*

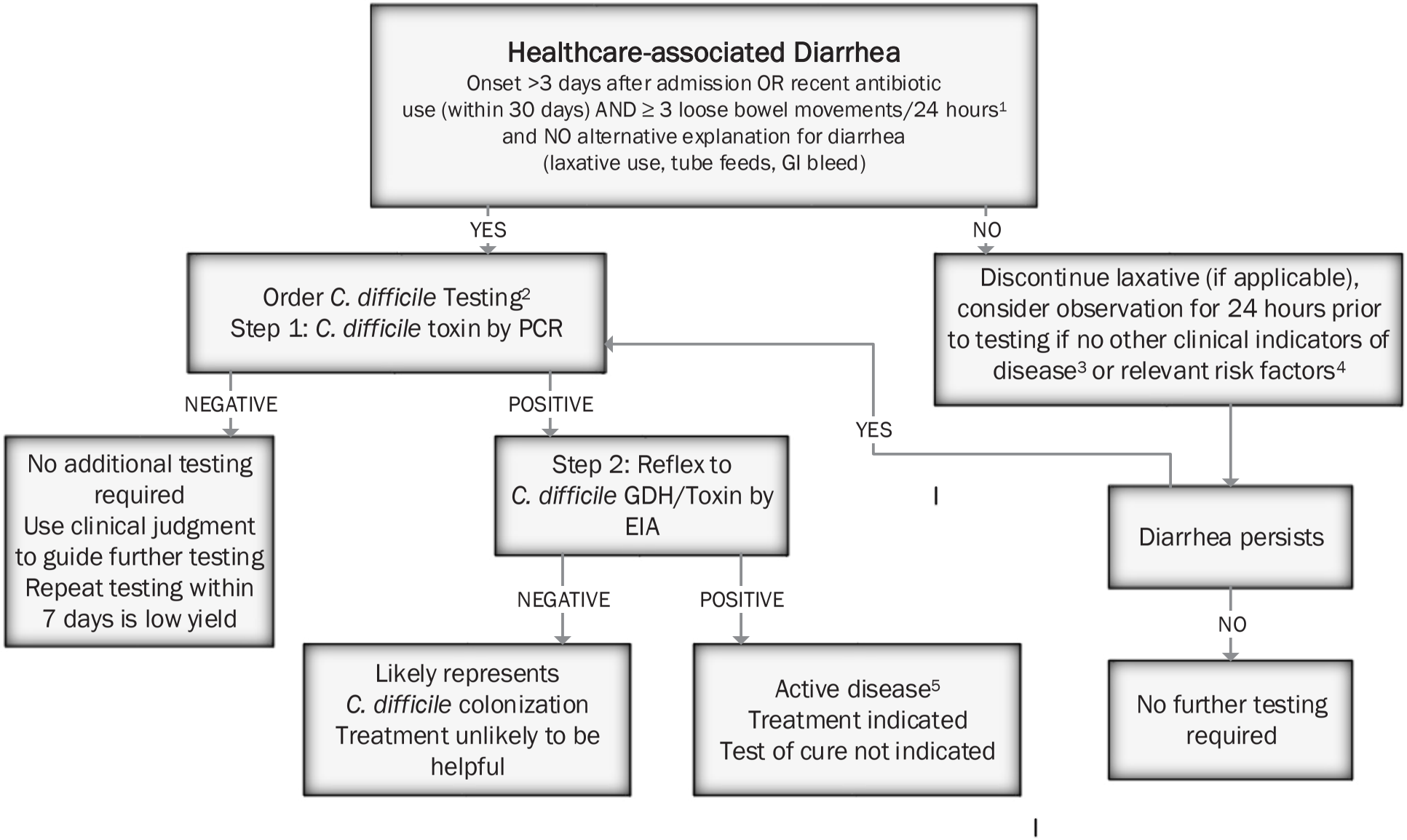
NEW TEST CODE

C. Diff Toxin Gene with Reflex (CDRFX) *(cont.)*	
Specimen Requirements:	Minimum Volume: 5g soft or liquid stool OR proctoscopic specimen. Container: • Sterile container for CDRFX (C diff toxin gene with reflex)DO NOT submit specimen in ParaPak containers • ParaPak containers for CSPCR or BSPCR • Swabs are NOT acceptable Collect: Formed stools are NOT acceptable.
Special Instructions:	• Specimens should be kept between 2°C and 25°C during transport • Protect against freezing or exposure to excessive heat • Do not send more than one specimen within 5 days. If multiple samples are sent within the 5 day period, they will be credited as duplicate specimens
Clinical Utility	*Clostridium difficile* is associated with antibiotic-induced colitis. The PCR assays detect the presence of the toxin gene. The toxin gene target is a good surrogate for detection of toxigenic *Clostridium difficile* but does not differentiate between colonization and active infection. . Asymptomatic colonization occurs in 10-20% of hospitalized patients. Adding the EIA assay will test for active toxin production indicating active infection.
Reference Range:	Presence of toxin is indicative of disease. It is important to consider any test results in conjunction with clinical symptoms. Because of the high prevalence of asymptomatic carriage of toxigenic *C. difficile* in infants, testing for CDI should never be routinely recommended for neonates or infants ≤12 months of age with diarrhea. CDI testing should not be routinely performed in children with diarrhea who are 1–2 years of age unless other infectious or noninfectious causes have been excluded.

C. difficile Testing Guideline – attached on page 9

For additional information, please contact Georgia Colasante, Manager, Microbiology at 877-402-4221.

C. difficile Testing Guideline



[1]Formed stools will be rejected by the laboratory
[2]Do not order multiple tests (i.e. C. diff x 3)
[3]Clinical indicators of *C. difficile* infection: abdominal pain, leukocytosis, fever
[4]Relevant risk factors include: recent antibiotic use, prior hospitalization, advanced age
[5]Active disease unlikely in children <5 years of age, particularly in the absence of risk factors

Reference:
McDonald LC et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018;66(7):e1-48

Revised 5/9/19

GENERAL INFORMATION

Urinary Tract Non-Gynecological Cytology: Adoption of the Paris System for Reporting Urinary Cytology

Effective Date:	**06/01/2019**
Content Provided:	The Paris System for Reporting Urinary Cytology was developed by a group of international expert pathologists and urologists to standardize the reporting of urinary cytology specimens. Understanding the goal of urinary cytology is to detect clinically significant urothelial carcinoma, the Paris System of reporting focuses on the presence or absence of high-grade urothelial carcinoma which is readily detected by cytology. We will join a large number of laboratories in the United States by adopting the Paris System which places urinary specimens into one of the following general diagnostic categories : • Unsatisfactory for evaluation • Negative for high-grade urothelial carcinoma • Atypical urothelial cells • Suspicious for high-grade urothelial carcinoma • High-grade urothelial carcinoma • Low-grade urothelial neoplasm • Positive for other diagnostic malignancy
Article Source:	"The Paris System for Reporting Urinary Cytology: the Quest to Develop a Standardized Terminology." Journal of the American Society of Cytopathology, vol. 5, no. 3

For additional information, please contact Dr. Lisa Dwyer-Joyce, HNL Pathology, at 610-402-8140 or Kelly Frankenfield, at 484-425-5854.