NEW YORK STATE

Parasitology Proficiency Testing Program

News and Notes

Recent reports in the literature have indicated a high rate of *Cryptosporidium* sp. false positive results associated with Rapid Cartridge Assays such as Meridian's Immunocard Stat and Remel's X/pect *Giardia/Cryptosporidium*. New York State was selected by CDC/APHL as one of four study sites to compare results obtained from RCAs with those of gold standard tests. In order to best evaluate the performance of the RCAs we will test all specimens from NY patients that are positive for *Cryptosporidium* by rapid cartridge or lateral flow assays. If your lab currently uses one of these tests you should have received a letter asking you to participate in this important study. Thank you to all of the labs who have submitted specimens to be part of this important study. Specimen collection is expected to continue through November. Please continue to submit specimens along with the submitting lab data collection form. If you have any questions concerning the study please contact the Parasitology Laboratory at 518-474-4177 or email us at parasite@wadsworth.org.

Parasitology Comprehensive
5 February 2013

The purpose of the New York State Proficiency Testing Program in the category of Parasitology-Comprehensive is to monitor the performance of applicant laboratories that detect and identify parasites in fecal emulsions, fecal smears, and blood films. This document reports the results for the February 2013 proficiency test in Parasitology-Comprehensive.

Sample Preparation and Quality Control

All emulsions and slides used in this test were prepared by a commercial source. The emulsions were dispensed into the vials from pools, which were continuously mixed during the loading process. Numerous samples of each test specimen were selected at random by the Wadsworth Center Parasitology Laboratory of the New York State Department of Health, and were assayed for quality and confirmation of organisms. Extensive quality control tests were also conducted by the supplying vendor and a detailed quality control report was submitted for inspection and verification. Samples were authenticated by at least 80% of participating laboratories and/or referee laboratories.

13-A (Helminthes Only)

Correct identification: *Schistosoma mansoni.*

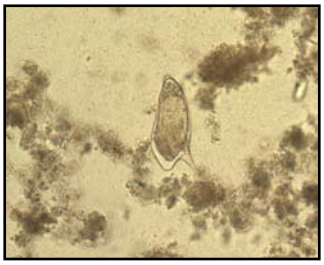
Results of Participating Laboratories

Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Schistosoma mansoni	99/102	97	10/10	Correct
No Parasites Seen	3	3	0	Incorrect

Quality Control and Referee Information

Participating and referee laboratories agreed that ***Schistosoma mansoni*** was the correct response (97 and 100%)**.** Quality control examination of 4% of this sample showed an average of 8 ova per coverslip. Other tests performed included a Direct Immunofluorescent Assay, which was negative for both *Cryptosporidium* sp. and *Giardia lamblia*, and a modified acid-fast stained slide, which was also negative.

Diagnostic Characteristics



Schistosoma mansoni is a blood trematode that infects veins in the colon and lower ileum as well as the liver. It is the most widespread of the human-infecting schistosomes and is found in South America and the Caribbean, Africa, and the Middle East. Schistosome eggs, which may become lodged within the host's tissues, are the major cause of pathology. Some of the deposited eggs reach the outside environment by passing through the wall of the intestine; the rest are swept into the circulation and are filtered out in the liver resulting in chronic liver disease. Humans become infected by skin penetration of cercariae which are released into water by the snail who are the intermediary hosts. These cercariae migrate through tissue until they invade a blood vessel. Diagnosis is made by detecting the characteristic eggs in stool. Eggs of *S. mansoni* are approximately 140 by 60 µm in size, and have a lateral spine.

13-B (Helminths Only)

Correct identification: *Hymenolepis nana*.

Results of Participating Laboratories

Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Hymenolepis nana	100/102	98	10/10	Correct
Cryptosporidium sp.	1	1	0	No Penalty
Hymenolepis diminuta	2	2	0	Incorrect

Quality Control and Referee Information

Participating and referee laboratories agreed that ***Hymenolepis nana*** was the correct response (98 and 100%). Quality control examination of 4% of this sample showed an average of 10 ova per coverslip. Other tests performed included a Direct Immunofluorescent Assay for *Giardia lamblia* and *Cryptosporidium* sp., which was negative for *Giardia lamblia* but detected low numbers of *Cryptosporidium* oocysts. A modified acid-fast stained slide was also negative.

Diagnostic Characteristics

Hymenolepis nana also known as the dwarf tapeworm is an intestinal cestode acquired by ingesting eggs from the environment or rarely by ingesting infected beetles. Internal autoinfection is also possible. *H. nana* is the only human tapeworm that doesn't have an intermediate host; transmission occurs from person-to-person. This cestode has a worldwide distribution and is more commonly seen in children. The diagnostic stage is the egg recovered in stool. These eggs are spherical, thin shelled, and typically measure 30 to 47 µm in diameter. The ova measured during quality control examination were a bit larger than this measuring approximately 50 µm. They have a six hooked oncosphere with two polar thickenings from which filaments arise. These filaments may be visible in the space between the embryo and the outer shell. Eggs of *H. nana* can be confused with the eggs of *Hymenolepis diminuta* and careful measurement with a calibrated ocular micrometer is essential. The eggs of *H. diminuta* are much larger measuring 70-85 µm.

12-M (All Parasites)

Correct identification: No Parasites Seen.

Results of Participating Laboratories

Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
No Parasites Seen	102/102	100	10/10	Correct

Quality Control and Referee Information

Participating and referee laboratories agreed that **No Parasites seen** was the correct response (100%). Quality control examination of 4% of this sample showed normal fecal elements and no organisms present. Other tests performed included a Direct Immunofluorescent Assay for *Giardia lamblia* and *Cryptosporidium* sp., which was negative for both organisms and a modified acid-fast stained slide, which was also negative.

12-N (All Parasites)

Correct identification: *Giardia lamblia.*

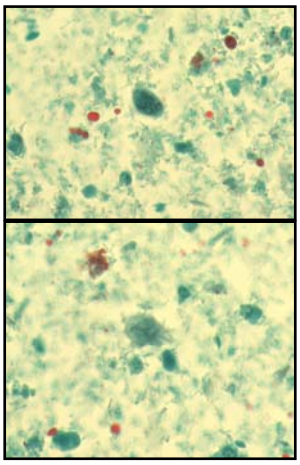
Results of Participating Laboratories

Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Giardia lamblia	102/102	100	10/10	Correct
Blastocystis hominis	1	1	0	Incorrect

Quality Control and Referee Information

Participating and referee laboratories agreed that ***Giardia lamblia*** was the correct response (100%). Quality control examination of 4% of this sample showed parasites in almost every 100 X oil immersion field. The predominant stage seen was the cyst but trophozoites were also present.

Diagnostic Characteristics



Giardia lamblia is the most commonly diagnosed flagellate in humans. It has a worldwide distribution and is more prevalent in children than in adults. Trophozoites are pear shaped and measure 10-20 µm. They have 2 nuclei, 4 pair of flagella, 2 axonemes, and 2 median bodies. The infective cysts are oval and measure 11-15 µm. They contain 4 nuclei usually located at one end, filaments, and median bodies. Infection occurs when food or water contaminated with fecal material containing *Giardia* cysts is ingested.

13-E (All Parasites)

Correct identification: *Plasmodium vivax.*

Results of Participating Laboratories

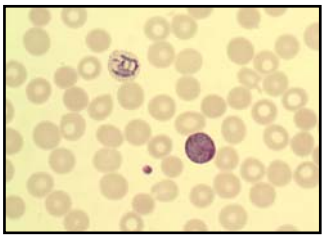
Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Plasmodium vivax	85*/98	87	9/10	Correct
Plasmodium ovale	11*	11	1	Incorrect
Plasmodium malariae	3*	3	0	Incorrect

*One participant reported both *P. v*ivax and *P. ovale*.

Quality Control and Referee Information

Participating and referee laboratories agreed that ***Plasmodium vivax*** was the correct response (87 and 90%). Quality control examination of 4% of this sample showed parasites in nearly every 100 X oil immersion field. Infected cells are enlarged and exhibit Schüffner's stippling. Both trophozoites and gametocytes are present.

Diagnostic Characteristics



Plasmodium vivax is the most common species of malaria to infect humans. It may account for as much as 80% of all malaria cases. It also has the widest distribution. Infected red cells are usually enlarged and stain paler than uninfected ones. They may also contain Schüffner's dots. The trophozoites, like the one in the image, are generally amoeboid and have a large chromatin. While *Plasmodium ovale* also enlarges the cell and has Scüffner's dots it generally has more compact cytoplasm, coarser pigment and infected cells can be fimbriated. *Plasmodium malariae* does not enlarge the cell, in fact infected cells are usually smaller than uninfected ones, and Schüffner's stippling is not present.

Scoring Information

Immunoassay Results

Cryptosporidium	13-A		13-B		13-C	
METHOD	**-**	**+**	**-**	**+**	**-**	**+**
Alere Giardia/Cryptosporidium Quik Check (TechLab)	4	0	4	0	4	0
MCC Para-Tect Cryptosporidium/Giardia DFA	1	0	1	0	1	0
Meridian ImmunoCard STAT Cryptosporidium/Giardia	26	0	26	0	28	0
Meridian Merifluor Cryptosporidium/Giardia	18	0	12	6*	18	0
Meridian Premier Cryptosporidium	1	0	1	0	1	0

Remel ProspecT Cryptosporidium EIA	16	0	15	1*	15	1
Remel Xpect Giardia/Cryptosporidium	4	0	4	0	4	0
TechLab Cryptosporidium II ELISA	2	0	2	0	2	0
TechLab/Wampole Test EIA	4	0	4	0	4	0

* Low numbers of *cryptosporidium* oocysts were observed on quality control examination.

Giardia	13-A		13-B		13-C	
METHOD	-	+	-	+	-	+
Alere Giardia/Cryptosporidium Quik Check (TechLab)	4	0	4	0	4	0
MCC Para-Tect Cryptosporidium/Giardia DFA	1	0	1	0	1	0
Meridian ImmunoCard STAT Crypto/Giardia	26	0	26	0	26	0
Meridian Merifluor Crypto/Giardia	14	0	14	0	14	0
Meridian Premier Giardia	1	0	1	0	1	0
Remel ProspecT Giardia EIA	24	0	22	2	24	0
Remel ProSpecT Giardia EZ	2	0	2	0	2	0
Remel Xpect Giardia	2	0	2	0	2	0
Remel Xpect Giardia/Cryptosporidium	4	0	4	0	6	0
TechLab/Wampole Test EIA	7	0	7	0	7	0
TechLab Giardia II ELISA	2	0	2	0	2	0

Distribution of Scores

Score	# of labs	% of labs
100	84	82
90-99	1	1
80-89	14	13
70-79	2	2

60-69	1	1

Answer Key

Sample	Correct Answer	Points
13-A	*Schistosoma mansoni*	20
13-B	*Hymenolepis nana*	20
13-C	No Parasites Seen	20
13-D	*Giardia lamblia*	20
13-E	*Plasmodium vivax*	20

TOTAL POSSIBLE POINTS 100

Grading

The answer key was derived from the response of all participating laboratories as per **CLIA Regulations**, Part 493, Subpart I, Section 493.917. These regulations can be viewed at wwwn.cdc.gov/clia/regs/toc.aspx . These regulations state that 80% or more of participating laboratories **or** referee laboratories must identify the parasite for it to be authenticated as a correct answer. Similarly, reporting of a parasite identified by less than 10% of the participating laboratories **or** referees is an incorrect response. Organisms that are not authenticated, but which were reported by more than 10% of the participating laboratories or referees, are "Unauthenticated" and are not considered for grading.

Each sample has a maximum value of 20 points. Credit is given according to the formula:

(# of Correct Responses/ (# of Correct Responses + # of Incorrect Answers)) X 100

Important Reminders

The next Parasitology Proficiency Test is scheduled for **May 7, 2013.** You are responsible for notifying us **before May 14, 2013** if you do not receive your samples. Proficiency test results must be electronically submitted through EPTRS by **May 21, 2013** or the laboratory will receive a score of zero. These requirements are stated in the NYS Proficiency Testing Handbook provided by the NYS Clinical Laboratory Evaluation Program or can be accessed via the Internet at:

http://www.wadsworth.org/labcert/clep/ProgramGuide/pg.htm