NEW YORK STATE

Parasitology Proficiency Testing Program

News and Notes

Cryptosporidium Rapid Cartridge Assays - Thank you to all of the labs who are submitting 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.

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. 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
14 May 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 May 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-F (ALL Parasites)

Correct identification: *Giardia lamblia.*

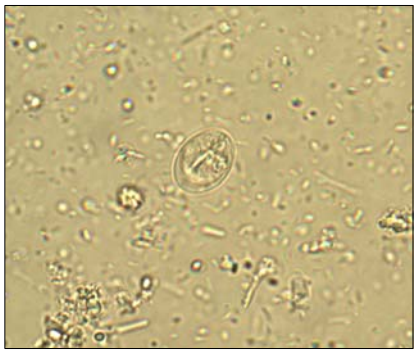
Results of Participating Laboratories

Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Giardia lamblia	102/102	100	10/10	Correct
Blastocystis hominis	11	11	3	No Penalty
Entamoeba coli	5	5	1	No Penalty

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 cysts in every 40 X field. Other tests performed included a Direct Immunofluorescent Assay, which was negative for *Cryptosporidium* sp. and positive for *Giardia lamblia*. A modified acid-fast stained slide was also negative. *Blastocystis hominis* and *Entamoeba coli* were also reported by 10% or greater of referee laboratories. These organisms were therefore graded as "No Penalty".

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. Although cysts and trophozoites can both be seen in wet mount preparations in this sample only cysts were observed during QC examination.

13-G (Helminths Only)

Correct identification: *Ascaris lumbricoides*.

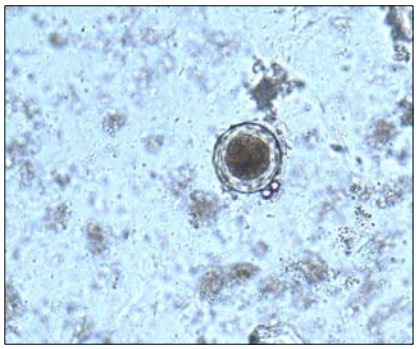
Results of Participating Laboratories

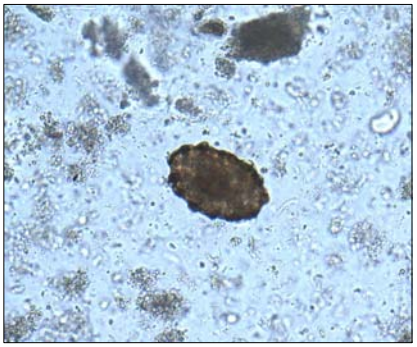
Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Ascaris lumbricoides	101/102	99	10/10	Correct
Hymenolepis nana	1	1	0	Incorrect
Schistosoma mansoni	1	1	0	Incorrect
No Parasites Seen	1	1	0	Incorrect

Quality Control and Referee Information

Participating and referee laboratories agreed that ***Ascaris lumbricoides*** was the correct response (99 and 100%). Quality control examination of 4% of this sample showed an average of 4 ova per coverslip. Both fertile and infertile eggs were seen

Diagnostic Characteristics





Ascaris lumbricoides is one of the most common intestinal nematode infections of man. It is most prevalent in warm moist climates but can also be found in cooler areas. Infection is acquired when embryonated eggs in contaminated soil are ingested. The fertilized eggs, like the one shown in the image on the top left, are round to oval, mammillated, and golden brown in color. They measure 45-75 µm by 35-50 µm. Occasionally they may lose their outer mammillated layer. Infertile eggs, shown on the top right, are larger, less broad, and have thinner shells. They measure 85-90 µm by 43-47 µm.

12-H (All Parasites)

Correct identification: *Paragonimus westermani*.

Results of Participating Laboratories

Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Paragonimus westermani	98/102	96	10/10	Correct
Fasciola hepatica/ Fasciolopsis buski	1	1	0	Incorrect
Diphyllobothrium latum	1	1	0	Incorrect
No Parasites Seen	1	1	0	Incorrect

Quality Control and Referee Information

Participating and referee laboratories agreed that ***Paragonimus westermani*** was the correct response (96 and 100%). Quality control examination of 4% of this sample showed 1-2 ova per coverslip.

Diagnostic Characteristics

The diagnostic stage of ***Paragonimus westermani*** is the characteristic egg found in stool or sputum. These eggs are yellow-brown, ovoid, and have a prominent operculum. They measure 80-120 µm by 45-70 µm and have a thickened shell at the abopercular end. Humans become infected when they ingest uncooked shellfish containing metacercariae. These metacercariae excyst in the duodenum and migrate into the lungs where they mature and release their eggs into the sputum. The eggs are then coughed up and released into the environment or swallowed and passed in the feces.

12-I (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	100/102	98	10/10	Correct
Entamoeba hartmanni	1	1	0	Incorrect
Endolimax nana	1	1	0	Incorrect
Fasciola hepatica/ Fasciolopsis buski	1	1	0	Incorrect

Quality Control and Referee Information

Participating and referee laboratories agreed that **No Parasites Seen** was the correct response (98 and 100%). Quality control examination of 4% of this sample showed normal fecal elements and no organisms present.

13-J (All Parasites)

Correct identification: *Plasmodium ovale* and *Plasmodium falciparum.*

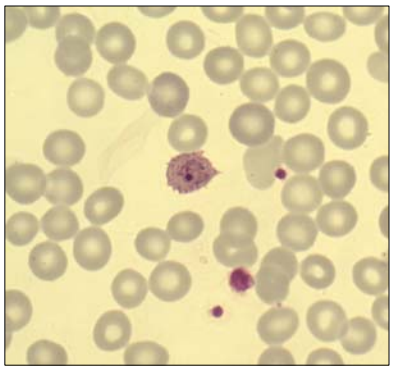
Results of Participating Laboratories

Organism reported	# of labs reporting	% of labs reporting	Referee results	Status
Plasmodium falciparum	83/98	87	10/10	Correct
Plasmodium ovale	72	75	7	No Penalty
Plasmodium vivax	9	9	0	Incorrect

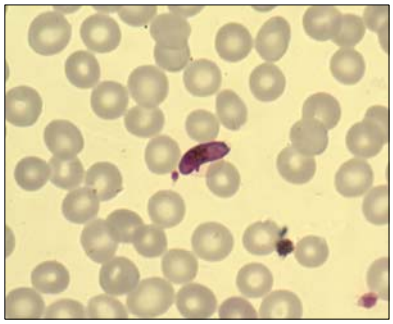
Quality Control and Referee Information

Participating and referee laboratories agreed that ***Plasmodium falciparum*** was the correct responses (87 and 100%). Quality control examination of 4% of this sample showed parasites in every 6-10 100 X oil immersion fields. Trophozoites and gametocytes of *Plasmodium falciparum* are present as well as trophozoites of *Plasmodium ovale*. The cells infected with *Plasmodium ovale* are slightly enlarged, fimbriated and have Schüffner's dots as shown in the first image below.

Diagnostic Characteristics



***Plasmodium* ovale** infections occur primarily in Central West Africa and some South Pacific Islands and account for fewer than 5% of all malaria cases. *P. ovale* malaria is usually less severe than other malarias and often ends in spontaneous recovery. The infected cells are usually enlarged, fimbriate, and have Schüffner's stippling. The cytoplasm of the trophozoites is usually less amoeboid than then that of P. vivax and the schizonts have 4-12 merozoites compared to 12-24 for *P. vivax*. The chromatin is usually very pronounced and the pigment is coarse.



Plasmodium falciparum is one of the four species of *Plasmodium* know to infect humans. It causes the most dangerous and severe form of malaria and is always considered to be a medical emergency. Death may occur rapidly if proper treatment is not started immediately. Its distribution is limited to the tropics, primarily Africa and Asia. *P. falciparum* invades all ages of RBCs and so the parasitemia can exceed 50%. The usual stages seen in the peripheral blood are rings and gametocytes. Schizogony occurs in the internal organs so it is rare to seen other stages although they may be present in cases of severe malaria. The infected RBCs are not enlarged nor do they contain Schüffner's dots. The rings are generally small, and may have one or two chromatin dots. Appliqué forms are also characteristic. Gametocytes are rounded to banana- shaped and contain a single well-defined chromatin and coarse rice-grain like pigment as shown in the image at left.

Starting with this PT event a separate set of samples was sent for antigen detection. These results are reported below.

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Scoring Information

Immunoassay Results

Cryptosporidium	13I-F		13I-G		13I-H	
METHOD	**-**	**+**	**-**	**+**	**-**	**+**
Alere Giardia/Cryptosporidium Quik Check (TechLab)	5	0	0	5	0	5
MCC Para-Tect Cryptosporidium/Giardia DFA	1	0	0	1	0	1
Meridian ImmunoCard STAT Cryptosporidium/Giardia	25	0	1	24	1	24
Meridian Merifluor Cryptosporidium/Giardia	18	0	2	16	1	17
Meridian Premier Cryptosporidium	1	0	0	1	0	1
Remel ProspecT Cryptosporidium EIA	16	0	0	16	0	16
Remel Xpect Giardia/Cryptosporidium	5	0	0	5	0	5
TechLab Cryptosporidium II ELISA	2	0	0	2	0	2
TechLab/Wampole Test EIA	4	0	0	4	0	4

Giardia	13I-F		13I-G		13I-H	
METHOD	**-**	**+**	**-**	**+**	**-**	**+**
Alere Giardia/Cryptosporidium Quik Check (TechLab)	0	5	0	5	5	0
MCC Para-Tect Cryptosporidium/Giardia DFA	0	1	0	1	1	0
Meridian ImmunoCard STAT Crypto/Giardia	0	25	1	24	25	0
Meridian Merifluor Crypto/Giardia	0	14	0	14	14	0
Meridian Premier Giardia	0	1	0	1	1	0
Remel ProspecT Giardia EIA	0	23	0	23	23	0
Remel ProSpecT	0	2	0	2	2	0

Giardia EZ						
Remel Xpect Giardia	0	2	0	2	2	0
Remel Xpect Giardia/Cryptosporidium	0	5	0	5	5	0
TechLab/Wampole Test EIA	0	7	0	7	7	0
TechLab Giardia II ELISA	0	2	0	2	2	0

Distribution of Scores

Score	# of labs	% of labs
100	83	81
90-99	6	6
80-89	11	11
70-79	1	1
60-69	1	1

Answer Keys

Sample	Correct Answer	Points
13-F	*Giardia lamblia*	20
13-G	*Ascaris lumbricoides*	20
13-H	*Paragonimus westermani*	20
13-I	No Parasites Seen	20
13-J	*Plasmodium ovale* *Plasmodium falciparum*	20

Sample	Correct Answer	Points
13I-F	*Giardia lamblia* positive *Cryptosporidium* sp. negative	20
13I-G	*Cryptosporidium* sp. and *Giardia lamblia* positive	20
13I-H	*Cryptosporidium* sp. positive *Giardia lamblia* negative	20

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 **October 1, 2013.** You are responsible for notifying us **before October 8, 2013** if you do not receive your samples. Proficiency test results must be electronically submitted through EPTRS by **October 15, 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