TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	9/29/2016
Department:	Core Lab	**Due Date:**	10/31/2016
		Implementation:	**11/1/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Malaria SGAH.M06 v5

Note: this has been converted to a system SOP

DHMH 1281 Laboratory Evidence of Certain Communicable Diseases
DHMH 4676 Infectious Agents Culture/Detection

Description of change(s):

Section	Reason
3.1	Add date and MR# to slide label
8.3	Add stain thin and thick smears. Add instructions to keep 1 set of slides at originating site. Clarified options if species cannot be determined
10.2	Add reporting of identification and parasitemia of Babesia
10.2	Clarified reporting of patients with repeat positive results. Added reporting and sending slides to Maryland DHMH (Dept. of Health & Mental Hygiene)
19	Added Maryland DHMH forms

Process changes for positive smears:

1. Report to county health department
   - Tech fills out form DHMH 1281
   - Fax to county office
   - File in designated binder

Note: only the first positive smear must be reported by fax (look in binder of previously faxed reports to see if patient was already reported)

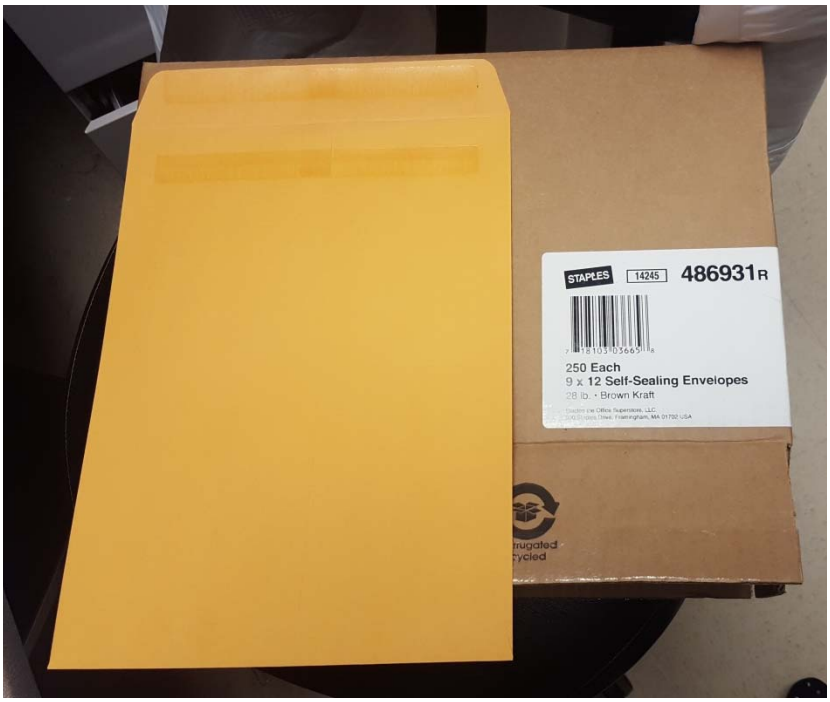
2. Send samples *(if slides are sent to another site for interpretation, then that site is responsible for sending the positive slides to the state)*
   - Tech fills out form DHMH 4676
   - Place slides in slide holder
   - Place slide holder and form in pre-addressed envelope
   - Place envelope with newborn screens for courier pickup

Forms and packing supplies will be kept in Micro

Revised SOP and new Forms will be implemented on November 1, 2016

Slide Holders

Packing envelope



Technical SOP

Title	**Malaria**
Prepared by	Ron Master Date: 5/11/2009
Owner	Ron Master Date: 5/11/2009

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 10/31/02

Quest Diagnostics Nichols Institute
Site: Shady Grove Medical Center, Washington Adventist Hospital
Title: **Malaria**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Malaria, thick and thin smears	Manual	MAL

Synonyms/Abbreviations
Malaria smear, Malaria ID, Malaria Parasites, *Plasmodium* species

Department
Microbiology

Form revised 10/31/02

2. ANALYTICAL PRINCIPLE

Examination of stained peripheral blood smears is used for screening and identifying malarial parasites, *Babesia*, trypanosomes, and microfilaria. Malarial and *Babesia* parasites infect circulating red cells and undergo various stages of development within the red cell. The Wright Giemsa stain highlights morphologic features of these stages.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	Slides are to be prepared when the patient presents with symptoms of malaria, and every 6 hours for 36 hours. Specimens obtained during the febrile state yield the greatest number of parasites in circulating blood. Prepare fresh finger stick thin smears and thick smears. **Thin smears:** Collect a small drop of blood near one end of a slide, and then spread the blood over the surface with a second slide. The thin, feathered end should be at least 2 cm long, and the film should occupy the central area of the slide, with free margins on each side. **Thick smears:** Prepare by touching the slide to the drop of blood (which should be rounded up on the finger). Rotate the slide to form a circular film about the size of a dime that is made up barely visible thorough wet smear. Allow for complete air-drying of smears. Label the frosted end of the slides using a pencil. Include the patient name, medical record number, date and accession number. The phlebotomist must hand the slides directly to a technologist. Refer to Phlebotomy procedure Malaria Smear Collection.

Component	Special Notations
Special Collection Procedures	**Collection procedure for the Germantown Emergency Department ONLY:** Because of limitations at Germantown for fingerstick collection, Malaria specimens may be collected in an EDTA lavender tube. Smears must be made at GEC within 30 minutes of collection in order to reduce distortion of the parasites and RBCs. The thin and thick smears (at least 2 of each) will be prepared at the Germantown ED and all of the smears and the EDTA tube will be sent to Shady Grove via STAT courier. The smears will be stained and examined at Shady Grove.
Other	A Malaria History Form is to be completed for each patient.

3.2 Specimen Type & Handling

Criteria		
Type -Preferred **-Other Acceptable**	Two thin and two thick smears **Note**: ONLY Germantown Emergency Department may accept an EDTA tube less than 30 minutes old. Thick and thin smears and the EDTA tube should be sent to Shady Grove.	
Collection Container	See section 3.1	
Volume - Optimum **- Minimum**	N/A N/A	
Transport Container and Temperature	Slide holder at room temperature	
Stability & Storage Requirements	Room Temperature:	1 month slides 30 minutes EDTA tube
	Refrigerated:	Unacceptable
	Frozen:	Unacceptable
Timing Considerations	N/A	
Unacceptable Specimens & Actions to Take	If specimen is too old test must not be performed. Improperly prepared or improperly labeled slides. Reject specimen and request recollection.	
Compromising Physical Characteristics	N/A	
Other Considerations	Treatment with anti-malarial or other antiparasitic drugs may reduce the sensitivity of the test.	

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier and Catalog Number
Giemsa Stain	Harleco – 620G-75
Buffer	Alphatec Giemsa (Malaria) Stain Buffer – 033-25

4.2 Reagent Preparations and Storage

Reagent	Giemsa Stain
Container	1 L bottle
Storage	15-30ºC
Stability	Stable until expiration date
Preparation	None

Reagent	Alphatec Giemsa (Malaria) Stain Buffer
Container	125 mL bottle
Storage	15-30ºC
Stability	Stable until expiration date
Preparation	None

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls

Appearance of blood cells is noted every time a patient's smear for malaria is performed.

Romanowsky Color Range

Chromatin of white blood cells	purple
Nuclei of parasitic protozoa	red
Basophilic cytoplasm of lymphocytes, monocytes, and parasitic protozoa	blue
Eosinophilic granules	pink
Neutrophilic granules	purple
Red blood cells	salmon pink (to bluish)
Bacteria	deep blue

Record QC results on Malaria Stain QC Form.
If controls are unacceptable do not report patient results, notify supervisor.

6.2 Control Preparations and Storage

N/A

6.3 Frequency

Each batch of patient smears is evaluated for proper staining characteristics.

6.4 Tolerance Limits and Criteria for Acceptable QC

A run is rejected if the WBCs, RBCs, and platelets on the thin smear are not stained adequately.

Rejected runs must be effectively addressed by corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed.

6.5 Documentation

Steps taken in response to QC failures must be documented.

6.6 Quality Assurance Program

N/A

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

None

7.2 Equipment

Microscope
Wescor Hematology Slide Stainer

7.3 Supplies

Immersion oil
Glass slides
Geimsa Stain
Buffer

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Thin Smears
1.	Allow smear to dry thoroughly before staining.
2.	Place patient thin smears on Wescor Hematology Slide Stainer. (see Hematology procedure for stainer instructions)
3.	Examine thin smears under 10X and 100X (oil immersion) to screen for the presence of malarial parasites, *Babesia*, microfilaria, and trypanosomes.
4.	At least 300 fields must be viewed with a 100X oil immersion lens for adequate assessment.

8.2	Thick Smears
1.	Allow smear to dry thoroughly before staining (at least 2 hours).
2.	Do not fix with alcohol or heat or dry in an incubator. Heat will prevent RBC lysis.
3.	Obtain working Giemsa solution. Into a Coplin jar add 49ml of the phosphate buffer, 1 ml of the Giemsa Blood Stain. Mix well before use. The working stain solution is stable for 24 hours.
4.	Place the thick smears directly into the working solution for 45-60 minutes. The water-based Giemsa stain disrupts the red cell membrane (laking) during the staining procedure exposing the parasites.
5.	Wash the smears by rinsing them with buffer (pH 7.0 to 7.2) for 3-5 minutes.
6.	Record pH of buffer on QC sheet.
7.	Air-dry in a vertical position.

8.3	Reading
1.	Scan the smear under low power first to detect presence of microfilaria or trypanosomes.
2.	Next read under oil immersion (100X objective).
3.	At least 300 fields under oil immersion must be examined.
4.	All shifts will stain thin and thick smears and screen thin smears for malaria, *Babesia*, microfilaria, and trypanosomes.
5.	If slides must be sent to another site for interpretation, keep 1 set of slides at the originating site.
6.	If positive and the species cannot be determined after review by a microbiology lead tech, supervisor or director, thin and thick smears may be sent to Washington Adventist Hospital to Dr. Beltaifa for pathologist review if she is available. If Dr. Beltaifa is not available, refer the slides to Chantilly.

9. CALCULATIONS

Parasitemia: In areas of the slide where the RBCs are evenly spread out over the entire field and not overlapping count the number of infected cells per field of 200 cells. Do this on 10 different areas on each thin smear. Calculate the average and divide by 2. The resulting number is the percentage of RBC's infected.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Smears

Smears are examined utilizing 10X and oil immersion lens (100x).

Read a minimum of 300 fields under oil immersion before determining that the thin smears are negative.

Thick smears are to be read before finalizing the report as negative. Thick smears are also a guide to the intensity of the infection. Thick smears allow a large amount of blood to be examined, increasing the detection of parasites in light infections. If parasites are detected on the thick smears, species determination must be made using the thin smear examination. This is determined by the recovery and identification of life cycle stages observed on the thin smear.

10.2 Reporting

10.2.1 General Information

Call both positive preliminary and final results to the nursing unit or physician. The call back information must be documented in the LIS.

Preliminary Reports:

If thin smears are negative, report: "Thin smear presumptive negative, thick smear and final report to follow". (NMLP1)

If thin smears are positive, report: "Presumptive positive, confirmation and identification to follow." (PMAL1)

If *Plasmodium falciparum* can be ruled out, report *Plasmodium* species, not *P. falciparum*. Send all of the smears (thin and thick) to Washington Adventist to Dr. Beltaifa for pathologist review.

If microfilaria or trypanosomes are seen, report their presence and send to Chantilly for confirmation.

*** Do not finalize the thin smear preliminary report in the LIS.**

Final Reports:

If negative, report: "No parasites seen. One set of blood films can not exclude the diagnosis of malaria." (NMAL1)

If positive report: 1. report genus and species for malaria or "*Babesia* species" if Babesia is seen.

2. report the level of parasitemia

Parasitemia:
Report the percentage of cells infected on all positive *Plasmodium* species or *Babesia* species. See section 9 for instructions on performing the calculation.

Report: "x.xx % Parasitemia"

Enter the number and % sign, then enter the code INF2 or enter using the Sunquest keyboard as in 10.2.2 below.

The call back information must be documented in the LIS.
* **More than one technologist must review all initial positive malaria smears. Repeated positive smears on the same patient do not require review by a second technologist.**

Document both tech codes on the LIS workcard.

Reporting to Maryland DHMH:
Smears positive for malaria or *Babesia* species must be reported by the technologist who reported the result to the Maryland Department of Health and Mental Hygiene by completing DHMH form 1281. Reports must be submitted within 1 working day (fax or mail).
Fax the form to the Montgomery County Health Department (240-777-4680).
If mailing, mark the sealed envelope "confidential" and send to

Montgomery County Health Department
2000 Dennis Ave
Suite 238
Silver Spring, MD 20992

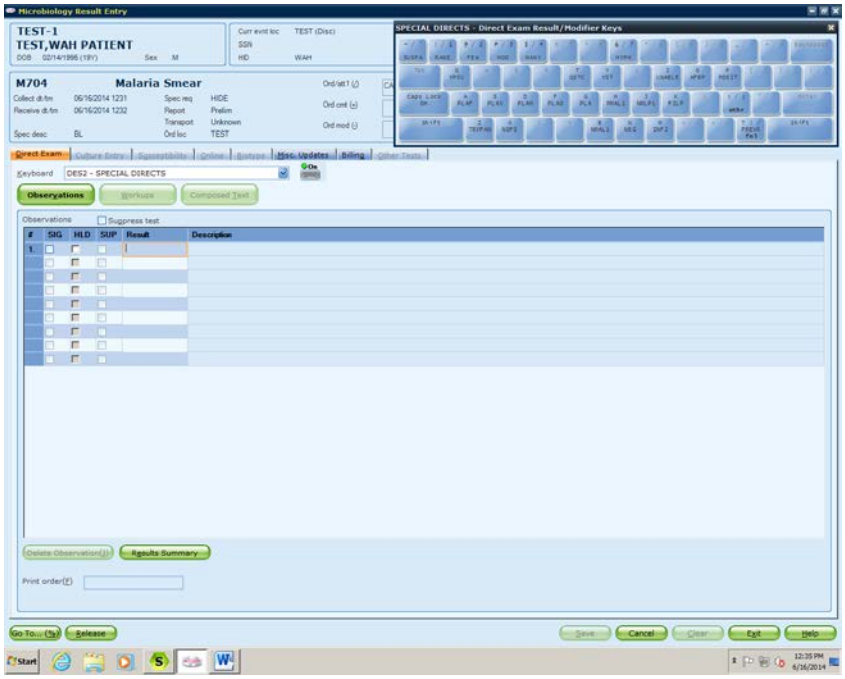
One set of thick and thin smears must be sent to the Maryland DHMH.

- Place slides in a plastic slide holder and package in a padded shipping envelope or box.
- Form DHMH 4676 must be completed and must accompany the slides.
- Address the package to Maryland Department of Health and Mental Hygiene, 201 W Preston St., Baltimore, MD 21201.
- Place package with the newborn screen samples for courier pickup

Form revised 10/31/02

10.2.2 LIS resulting

1. Use GUI function **Micro Result Entry**.
2. Key in the accession # and click on **SELECT.**
3. Press on F8 to display the resulting keyboard. Note: to turn off the keyboard press F8 again.



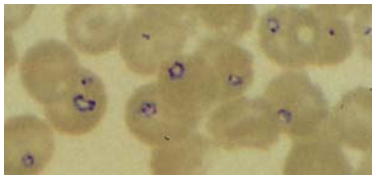
4. Click on the Micro keyboard to enter in your results
5. If you have a positive malaria smear then result as follows:
    a. **Observation #: Organism -** Click on the organism from the Micro keyboard, then press the tab key until you are at the next observation line in the **result** field.
    b. **Observation #: Infectivity rate -** Press **; twice** (the first ; will not display on the screen but the second one will) and then free text the infectivity rate (example 2.0 %), then press the tab key. From the Micro keyboard, click on the **M** key. This will add **–Parasitemia** to your infectivity rate.
    c. **Observation #:** ;CBACK <cr> (expands to 'Called to and read back by:) ;; add free text call documentation <cr> <cr>
6. Press the tab key twice so that your cursor is in the next result field.
7. If this is a prelim, click on **SAVE**
8. If this is a final, click on the **/ (final)** key from the Micro Keyboard and then click on **SAVE**.

* Each call must be documented. Do not delete previous call back information.

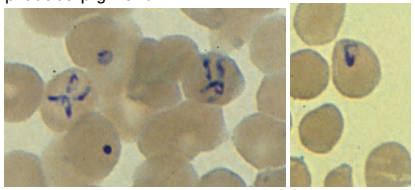
10.3 Interpretation of data

Morphological Characteristics of *Plasmodium falciparum* and *Babesia* species:

Appearance of parasite	*Plasmodium falciparum*	*Babesia* species
Size	Small (1/4 to 1/3 RBC diameter, 3-5 µm)	Tiny to small (1/8 to 1/4 RBC diameter, 1-5 µm)
Shape	Consistent oval to round ring	Pleomorphic: pear-shaped to round ring
Appliqué Forms	Common, either marginal or bulging forms	Common, either marginal or bulging forms
Number of Chromatin dots	1 to 2	1 to many ("string of pearls")
Multiple rings/RBC	Common	Common; two adjacent parasites may appear to be split into mirror images
Tetrads	No	Rarely seen
Appearance of RBCs	Normal size and shape	Normal size and shape
Parasite stages present	Ring: trophozoite with pigment (in heavy infections); banana-shaped gametocytes (rarely found)	Ring: late ring or trophozoite with no pigment, may contain a white central vacuole not seen in *Plasmodium*



A: *Babesia microti* infection, Giemsa-stained thin smear. The organisms resemble *Plasmodium falciparum*; however *Babesia* parasites present several distinguishing features: they vary more in shape and in size; and they do not produce pigment.

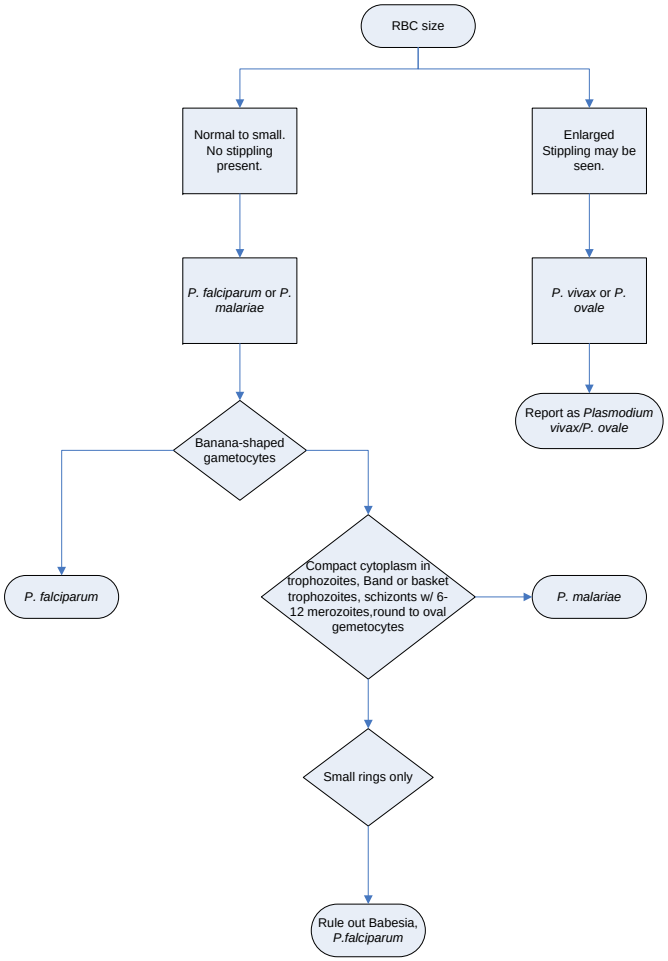


B.and C: Infection with *Babesia*. Giemsa-stained thin smears. Note in **B** the tetrad (left side of the image), a dividing form pathognomonic for *Babesia*. Note also the variation in size and shape of the ring stage parasites (compare **B** and **C**), and the absence of pigment.

Morphology of *Plasmodium* species in Wright-Giemsa stained smears:

Characteristics	*P. falciparum*	*P. vivax*	*P. ovale*	*P. malariae*
Size and shape of infected erythrocytes	Normal size and shape	Enlarged up to twofold, may be oval	Normal to enlarged, frequently oval, may be fimbriated	Small to normal size, normal shape
Stippling	Occasional Mauer's dots, less numerous than Schuffner's	Schuffner's dots (stippling) usually present, except in rings	James' stippling, darker than Schuffner's, present in all stages, including rings	Zeiman's dots rarely seen; requires deliberate over staining
Stages seen in peripheral blood	Rings and gametocytes	All	All	All
Multiply infected erythrocytes	Common	Occasional	Occasional	Rare
Early trophozoites	Delicate ring, frequently with two small chromatin dots, often at the edge of the erythrocyte	Ring up to 1/3 diameter of the erythrocyte; larger chromatin dot than *P. falciparum*	Similar to *P. vivax*	Smaller that *P. vivax*; otherwise similar
Mature trophozoites	Not seen in peripheral blood	Amoeboid shape, fine golden brown pigment	Similar to *P. vivax* except less amoeboid, pigment darker brown	Compact cytoplasm, oval, round, or band-shaped, dark brown pigment
Schizonts	Not seen in peripheral blood	12-24 merozoites	8-12 merozoites	6-12 merozoites often radically arranged around central pigment in a rosette form
Gametocytes	Crescent of banana-shaped	Round to slightly oval	Round to slightly oval	Round to slightly oval
Most characteristic findings	Absence of mature trophozoites and schizonts; normal size of infected erythrocytes; multiply infected RBCs; appliqué forms; banana-shaped gametocytes	Enlarged infected erythrocytes; Schuffner's dots frequently present; amoeboid trophozoite; 12-14 merozoites in each schizont	Normal to enlarged, oval or fimbriated infected RBCs, James' stippling may be seen in rings; schizonts with 8-12 merozoites	Normal size of infected erythrocytes; no stippling; "band" trophozoite; rosette schizont with 6-12 merozoites

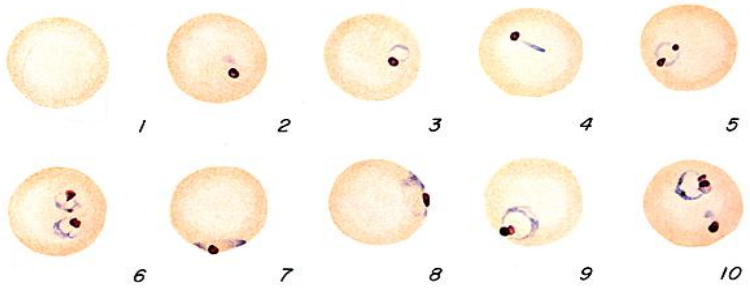
Malaria Identification



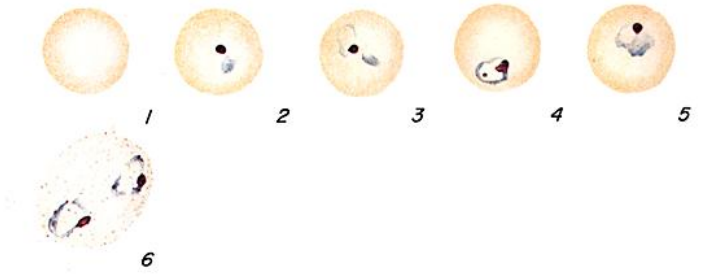
Always calculate and report % parasitemia

Ring Stage Parasites

Plasmodium falciparum: Rings



Plasmodium vivax: Rings

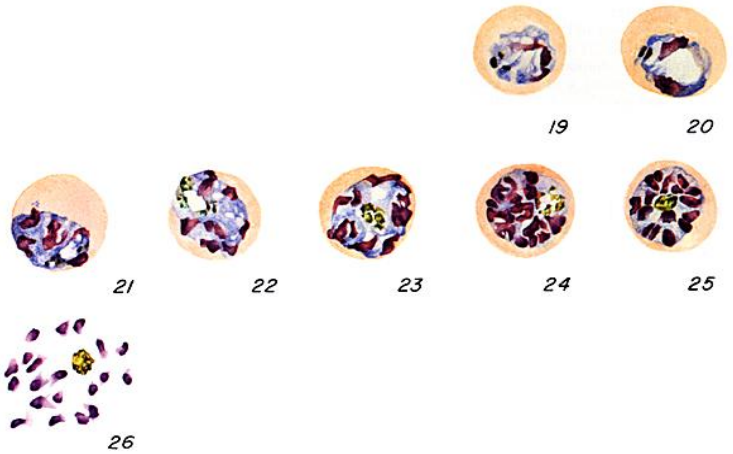


Plasmodium ovale: Rings

***Plasmodium malariae*: Rings**

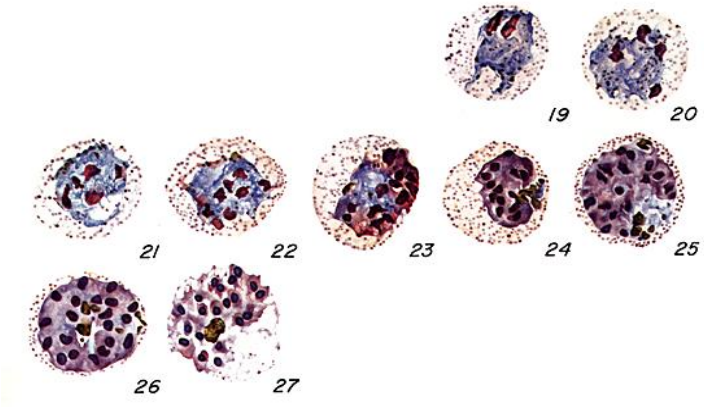
Schizonts

***Plasmodium falciparum*: Schizonts (usually not seen in blood)**

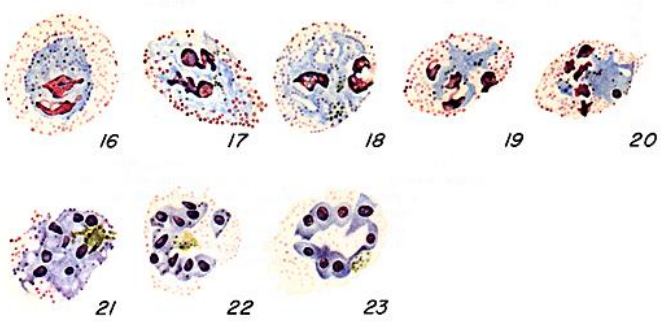


Form revised 10/31/02

***Plasmodium vivax*: Schizonts**

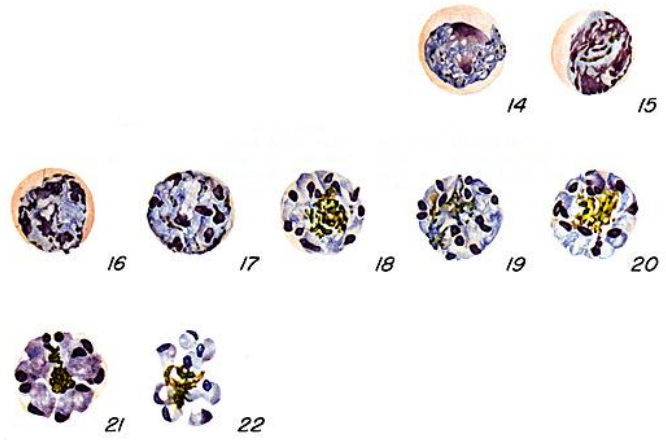


***Plasmodium ovale*: Schizonts**



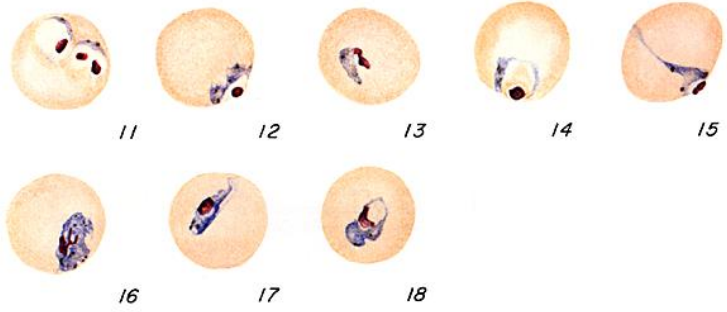
Form revised 10/31/02

***Plasmodium malariae*: Schizonts**

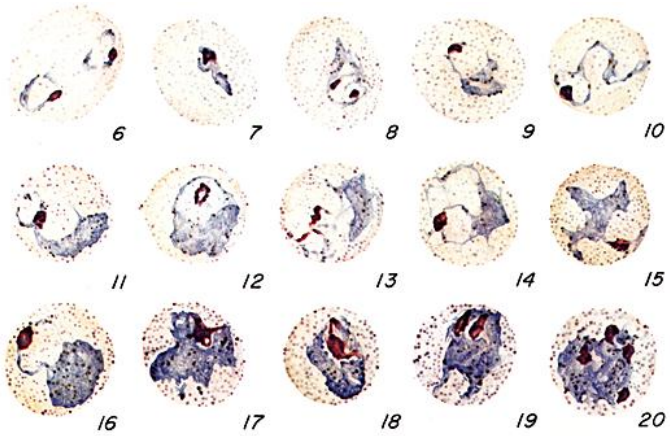


Trophozoites

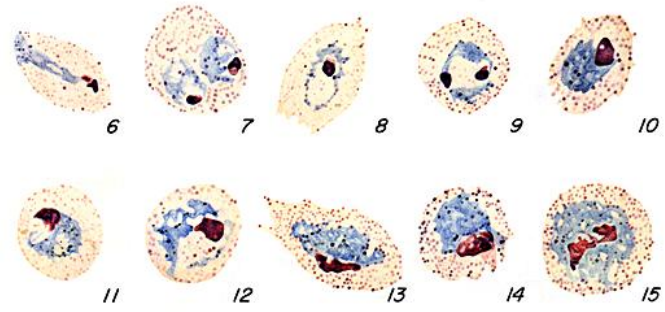
***Plasmodium falciparum*: Trophozoites (early forms may be seen but later forms usually not seen in blood)**



***Plasmodium vivax*: Trophozoites**

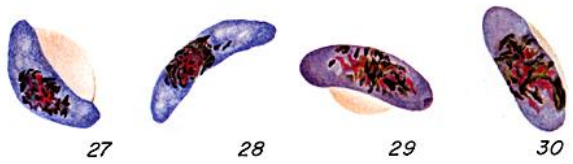


***Plasmodium ovale*: Trophozoites**

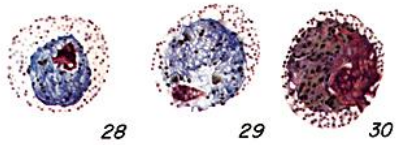


Gametocytes

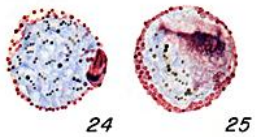
Plasmodium falciparum: Gametocytes



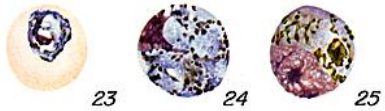
Plasmodium vivax: Gametocytes



Plasmodium ovale: Gametocytes

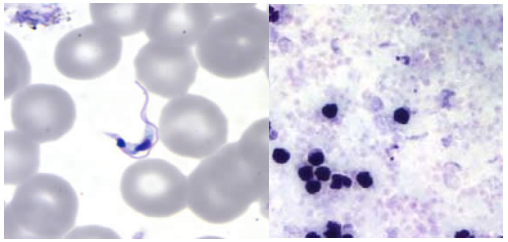


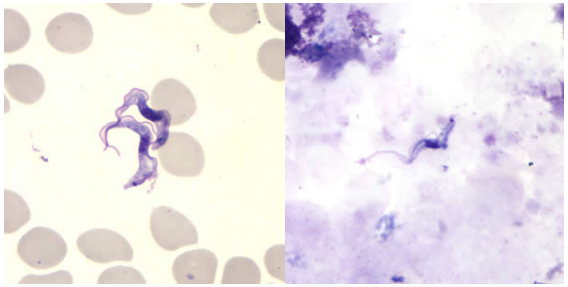
Plasmodium malariae: Gametocytes



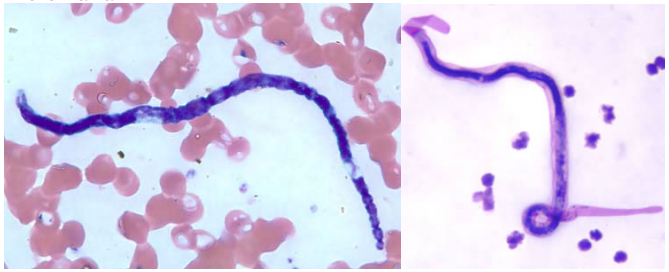
Morphology of trypanosomes and microfilaria.

Trypanosomes





Microfilaria



10.5 Rounding / Units of Measure / Clinically Reportable Range (CRR)

N/A

10.6 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results such as an unusually high percentage of abnormal results.

10.7 Repeat Criteria and Resulting

N/A

11. EXPECTED VALUES

11.1 Reference Ranges

No parasites seen.

11.2 Critical Values

Any positive smear

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Malaria is a disease of worldwide importance characterized by fever, anemia and splenomegaly. Although four species of the genus *Plasmodium (P. falciparum, P. vivax, P. malariae,* and *P. ovale)* infect humans, malaria is clinically two diseases; the benign type due to *P. vivax, P. malariae,* and *P. ovale,* and the malignant type due to *P. falciparium.*

Determination of parasitemia becomes important when therapy is initiated. The patient's parasitemia is monitored so that possible cases involving drug-resistant strains of *P. falciparium* may be detected. In those cases where the patient is hospitalized, monitoring of the parasitemia should be performed at 24, 48 and 72 hours after initiating therapy. Generally, if the malarial strain is susceptible to the therapeutic regime, the parasitemia will drop significantly within the first 24 hours (often by 50% or more).

Babesia is a malaria-like disease characterized by fever, chills, headache, lethargy and myalgia. Hemolytic anemia and hemoglobinuria are typical and may be sever. The disease is transmitted by the bite of hard ticks of the family Ixodidae. This disease is suspected when individuals have traveled through tick-infested areas and present with a malaria-like illness. The disease becomes apparent 1-3 weeks after the bite of an infectious tick. In splenectomized and immunocompromised patients this disease may be fatal. Determination of % parasitemia helps direct therapy. In severe parasitemia (>10%), exchange transfusion may be considered.

Parasitemia and Clinical Correlation

Parasitemia	Parasites /uL	Clinical Correlation
0.0001-0.0004%	5 – 20	Number of organism that are required for a positive thick film (sensitivity)
0.002%	100	Patients may be symptomatic below this level
0.2%	10,000	Level above which immune patients will exhibit systems
2%	100,000	Maximum parasitemia of *P. vivax* and *P. ovale* (infect young RBSs only)
2-5%	100,000 – 250,000	Hyperparasitemia, severe malaria, increased mortality
10%	500,000	Exchange transfusion may be considered, high mortality

13. PROCEDURE NOTES

- **FDA Status:** LDT without message
- **Validated Test Modifications:** None

Any alcohol left on the skin prior to collection may fix the red cells and then they will not clear in the staining procedure.

Do not dry smears using heat, as this will fix the red cells.

Slides prepared from EDTA blood are not optimal as they may cause distortion in the parasites, making identification difficult. However, the Emergency Center at Germantown is the ONLY location where an EDTA specimen is acceptable rather than fingertip smears.

Organisms are most likely to be detected if the smears are obtained immediately upon the onset of fever, or immediately before the fever is anticipated. In patients with a strong clinical history, but repeatedly negative results, multiple sampling throughout the fever may prove successful.

Platelets sitting on top of red blood cells may have the appearance of a ring form of malaria.

Precipitated stain may obscure malarial forms on the smear.

Identification to species should not be based solely on the examination of the thick smear preparation. Both thick and thin smears are required for a comprehensive blood parasite examination.

The patient's travel history may provide helpful information in the identification of malaria, *Babesia* species, and other blood parasites. Blood parasites are endemic to certain regions of the world; knowing what countries the patient has visited will aid in diagnosis.

The chart below can be used as a guide for diagnosis. It is not to be used as the primary diagnostic factor:

Blood Parasite	Endemic Area(s)
Plasmodium falciparum	Africa, Asia, Indian subcontinent, South America (Tropical areas worldwide)
Plasmodium vivax	Tropical and Temperate areas worldwide
Plasmodium malariae	Africa, Asia, Indian subcontinent, South America (Tropical areas worldwide)
Plasmodium ovale	West Africa, India, South America, some South Pacific Islands

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

N/A

14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

Hematology Slide Stainer Cytocentrifuge, Wescor Aerospray; Hematology procedure
Resulting Microbiology Direct Exams, Microbiology procedure
Malaria Smear Collection, Phlebotomy procedure
Malaria Smear Collection – GEC Only, GEC Microbiology procedure
Malaria History Form (AG.F289)
Reportable Results to State and Outside Agencies, Laboratory policy

17. REFERENCES

1. Jacobs DS, et al, Laboratory Test Handbook, 4th edition, Hudson, OH: Lexi-Comp, Inc., 1999, pp. 332-333.
2. Kjeldsberg C, et al, Practical Diagnosis of Hematologic Disorders, 2nd edition, Chicago, IL: ASCP Press, 1995, pp. 172-173.
3. Atlas of Human Parasitology, 3rd edition, Chicago, IL: ASCP Press.

4. Hansheid, T. 1999. Diagnosis of malaria: A review of alternatives to conventional microscopy. Clin. Lab. Haematol. 21:235-245.
5. Wilkinson, R.J., J.L. Brown, G. Pasvol, P.L. Chiodini, and R.N. Davidson. 1994. Severe falciparum malaria: predicting the effect of exchange transfusion. Q.J. Med. 87:553-557.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP M028.005		
000	10/12/09	10.2.2	LIS upgrade to GUI system	A. Sears	R. Master
000	10/12/09	16	Added procedure for resulting	L. Barrett	R. Master
001	9/19/2011	3.1, 13	Added use of EDTA specimen at GEC	C. Reidenauer	R. Master
001	9/19/2011	4.2	Changed storage temperature for buffer	R. Master	R. Master
001	9/19/2011	8	Remove statement regarding pkg insert	L. Barrett	R. Master
001	9/19/2011	8.3	Added trypanosomes and microfilaria	R. Master	R. Master
001	9/19/2011	11.2	Update title to local terminology	L. Barrett	R. Master
002	11/19/12	9 10.2.1 10.2.2	Change report to "Parasitemia followed by the % infectivity". Changed steps on how to report the % infectivity (English Text code first then free text the rate %)	M. Sabonis	R. Master
003	7/17/14	3.1, 3.2	Changed EDTA time to 30 min. Removed sending all thick smears to WAH.	R. Master	R. Master
003	7/17/14	8.2	Add stability of working solution. Removed comment to send all think smears to WAH.	R. Master	R. Master
003	7/17/14	8.3, 10.2	Add to send to Dr. Beltaifa if species could not be determined.	R. Master	R. Master
003	7/17/14	9	Clarified calculation	R. Master	R. Master
003	7/17/14	10.2	Add preliminary report of *Plasmodium* species, not *P. falciparum*.	R. Master	R. Master
003	7/17/14	10.2.1	Change order of reporting parasitemia, deleted redundant calculation	R. Master	R. Master
003	7/17/14	10.2.2	Add instructions for entering results in GUI version of LIS	R. Master	R. Master
003	7/17/14	10.3	Added flow chart	R. Master	R. Master
003	7/17/14	16	Update titles, add form number	L. Barrett	R. Master
003	7/17/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L. Barrett	R. Master
4	9/20/16	Header	Add WAH	L. Barrett	R. Master
4	9/20/16	3.1	Add date and MR# to slide label	R. Master	R. Master

4	9/20/16	4	Update to new standard labeling instruction	L Barrett	R. Master
4	9/20/16	8.3	Add stain thin and thick smears. Add instructions to keep 1 set of slides at originating site. Clarified options if species cannot be determined	R. Master	R. Master
4	9/20/16	10.2	Add reporting of identification and parasitemia of Babesia	R. Master	R. Master
4	9/20/16	10.2	Clarified reporting of patients with repeat positive results. Added reporting and sending slides to Maryland DHMH	R. Master	R. Master
4	9/20/16	10.6	Move patient review from section 6	R. Master	R. Master
4	9/20/16	15	Update to new standard wording	L Barrett	R. Master
4	9/20/16	16	Added SOP Reportable Results to State and Outside Agencies	R. Master	R. Master
4	9/20/16	19	Added Maryland DHMH forms	R. Master	R. Master

19. ADDENDA

Maryland form DHMH 1281 (see Attachments pane in SmartSolve)
Maryland form DHMH 4676 (see Attachments pane in SmartSolve)

CONFIDENTIAL REPORT: LABORATORY EVIDENCE OF CERTAIN COMMUNICABLE DISEASES
USE FOR REPORTING TO: MARYLAND STATE DEPARTMENT OF HEALTH AND MENTAL HYGIENE

USE FOR ALL COMMUNICABLE CONDITIONS EXCEPT HIV and CD4. (Use form DHMH 4492 for HIV and CD4.)

(PLEASE TYPE OR PRINT USING BLACK INK.)

PATIENT LAST NAME	FIRST	MIDDLE INITIAL	HOSPITAL NUMBER	PREGNANT? (FEMALE) YES ☐ NO ☐

DATE OF BIRTH	AGE	SEX	ETHNICITY HISPANIC ☐ NON-HISPANIC ☐	RACE

NUMBER STREET	APT	CITY	STATE ZIP	COUNTY	(AREA CODE) PHONE

ORDERING PROVIDER NAME

NUMBER STREET	SUITE	CITY	STATE ZIP	COUNTY	(AREA CODE) PHONE (AREA CODE) FAX

ORDERING FACILITY NAME

NUMBER STREET	SUITE	CITY	STATE ZIP	COUNTY	(AREA CODE) PHONE

DATE SPECIMEN COLLECTED	DATE SPECIMEN RECEIVED	DATE RESULTED	LAB ACCESSION NUMBER

TYPE OF SPECIMEN

Sputum ☐ Stool ☐ Pharyngeal Swab ☐ Discharge ☐

Blood ☐ CSF ☐ Washing ☐ Other (Specify) _____

SITE OF SPECIMEN (CERVIX, EYE, ETC.)

NAME OF TEST	TEST NUMBER OR CODE

RESULT WITH REFERENCE RANGE & INTERPRETATION

(IF AN ORGANISM RESULT: INCLUDE SPECIES, SEROGROUPING, OR OTHER SUBTYPING IF KNOWN)

IF A HEPATITIS C RESULT:

Signal to Cut-Off Ratio (SCO)	Critical Value for SCO	Hepatitis A IgM Result	Hepatitis B Core IgM Result

LAB NAME (LAB PERFORMING THE TEST)	LAB CLIA NUMBER

LAB ADDRESS

LAB DIRECTOR	LAB (AREA CODE) PHONE	DATE OF REPORT

DHMH 1281 **SEND TO YOUR LOCAL HEALTH DEPARTMENT**

Revised JAN 26, 2012 For more forms or information, go to http://ideha.dhmh.maryland.gov/SitePages/what-to-report.aspx

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Robert A. Myers, Ph.D., Director

STATE LAB
Use Only

INFECTIOUS AGENTS: CULTURE/DETECTION

TYPE OR PRINT REQUIRED INFORMATION OR PLACE LABELS ON ALL FOUR COPIES

☐EH ☐FP ☐MTY/PN ☐NOD ☐STD ☐TB ☐CD ☐COR
Health Care Provider
Address
City County
State Zip Code
Contact Name:
Phone# Fax#
Test Request Authorized by:

Patient SS# (last 4 digits):
Last Name ☐SR ☐JR ☐Other_____
First Name M.I. Maiden:
Date of Birth (mm/dd/yyyy) / /
Address
City County
State Zip Code

Sex: ☐Male ☐Female ☐Transgender M to F ☐Transgender F to M
Ethnicity: Hispanic or Latino Origin? ☐yes ☐no
Race: ☐American Indian/Alaska Native ☐Asian ☐Black/African American ☐Native Hawaiian/other Pacific Islander ☐White
Case # DOC# Outbreak # Submitter Lab#
Collect Date: Collect Time: ☐am ☐pm Onset Date:
Reason for Test: ☐Screening ☐Diagnosis ☐Contact ☐Test of Cure ☐2-3 Months Post Rx ☐Suspected Carrier ☐Isolate for ID ☐Release
Therapy/Drug Treatment: ☐No ☐Yes Therapy/Drug Type:_____ Therapy/Drug Date:_____

SPECIMEN CODE	BACTERIOLOGY
	Bacterial Culture - Routine
	Additional specimen codes: _____ _____
	Bordetella pertussis
	Group A Strep
	Group B Strep Screen
	C. difficile Toxin
	Diphtheria
	Foodborne Pathogens *(B. cereus, C. perfringens, S. aureus)*
	Gonorrhea Culture:Incubated?☐yes ☐no
	Hrs. incubated:___ Add'l specimen codes:__ __
	MRSA (rule out)
	VRE (rule out)
	ENTERIC INFECTIONS
	Campylobacter
	E. coli O157 typing
	Enteric Culture - Routine (Salmonella, Shigella, *E. coli* O157, Campylobacter)
	Salmonella typing
	Shigella typing
	V. parahaemolyticus
	Yersinia
	REFERENCE MICROBIOLOGY
	ABC'S (BIDS) #_____
	Organism: _____
	Bacteria Referred Culture for ID
	Specify: _____

SPECIMEN CODE	SPECIAL BACTERIOLOGY
	Legionella Culture
	Leptospira
	Mycoplasma
	MYCOBACTERIOLOGY/AFB/TB
	AFB/TB Culture and Smear
	AFB/TB Referred Culture for ID
	M. tuberculosis Referred Culture for Genotyping
	Nucleic Acid Amplification Test for *M. tuberculosis* Complex (MTD)
	PARASITOLOGY
	Blood Parasites:_____
	Country visited outside US:_____
	Ova & Parasites:Immigrant? ☐yes ☐no
	Cryptosporidum
	Cyclospora/Isospora
	Microsporidium
	Pinworm
	VIRUS ISOLATION/CHLAMYDIA
	Adenovirus*
	Arbovirus Panel (WNV, EEEV, SLEV)
	Chlamydia trachomatis
	Cytomegalovirus (CMV)
	Enterovirus (Inc. Echo & Coxsackie)
	Herpes Simplex Virus (Types 1 & 2)
	Influenza (Types A & B)*
	Parainfluenza (Types 1, 2 & 3)*
	Respiratory Syncytial Virus (RSV)*
	Varicella (VZV)

MAY INCLUDE RESPIRATORY SCREENING PANEL.

Comments:

SPECIMEN CODE	RESTRICTED TESTS Pre-approved submitters only
	Chlamydia trachomatis/GC NAAT
	Chlamydia trachomatis only/NAAT
	Norovirus ** (see comment on back)
	OTHER TESTS FOR INFECTIOUS AGENTS
	Test name:_____

Prior arrangements have been made with the following DHMH Laboratories Administration employee:
_____

SPECIMEN CODE:
PLACE CODE IN BOX NEXT TO TEST

B	**Blood**
BW	**Bronchial Washing**
CSF	**Cerebrospinal Fluid**
CX	**Cervix/Endocervix**
E	**Eye**
F	**Feces**
N	**Nasopharynx/Nasal**
P	**Penis**
R	**Rectum**
SP	**Sputum**
T	**Throat**
URE	**Urethra**
UFV	**Urine (First Void)**
UCC	**Urine (Clean Catch)**
V	**Vagina**
W	**Wound**
O	**Other:**

ORIGINAL