Diagnostic Testing for Parasitic Diseases at CDC

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https://www.cdc.gov/parasites/lab_science.html
Diagnostic Parasitology Laboratory

**Who can submit specimens?**
- State health departments
  - Original submitters (e.g. hospitals, health care providers) MUST contact local/state health department)
- Other federal agencies

**DPDM website**
- [https://www.cdc.gov/parasites/index.html](https://www.cdc.gov/parasites/index.html)
- See Information for Specific Groups > Laboratory Scientists

**Test directory**
- [https://www.cdc.gov/laboratory/specimen-submission/list.html](https://www.cdc.gov/laboratory/specimen-submission/list.html)
Current status of test systems – March 2023

Molecular
- Chagas disease Molecular Detection
- Leishmania Molecular Identification
- Malaria Molecular Identification
- Babesia Molecular Detection
- Angiostrongylus cantonensis Molecular Detection

Serology
- Chagas disease (EIA, IB, IFA)
- Paragonimiasis (IB)
- Fascioliasis (IB)
- Baylisascaris (IB)
- Cysticercosis (IB)
- Strongyloides (EIA)
- Schistosomiasis (IB)
- Echinococcosis (IB)
- Babesiosis (IFA)
- Filariasis (EIA)
- Toxocariasis (EIA)

Morphology
- Ova and Parasite
- Physical specimens
- Telediagnosis
- Trichomonas Susceptibility

Online
Pending resumption
Submitting specimens to CDC

• See Test Directory for acceptable conditions
  • Time from collection
  • Storage and shipping temperature
• Sample submission form; Form 50.34
• Send email to CDC POCs or parasiteslab@cdc.gov before sending specimens to obtain pre-approval
  • Ensures up-to-date submission/shipping information
• Do not ship prior to federal holidays or weekends

Selected Specimen Conditions

• Serum for serology
  • Send frozen (≤ -20ºC) on dry ice
  • Up to 8 weeks from collection

• Whole blood for molecular assays
  • Send refrigerated (2-8ºC) on cold packs
  • Time from collection varies

• Tissue for molecular assays
  • Fresh tissue should (preferably) be sent frozen (≤ -20ºC) on dry ice
  • Up to 30 days from collection
Coordinating with original submitters

• **Jurisdiction specific requirements**
  • Do specimens need to be sent to SPHL?
  • Assistance with SPHL information on 50.34

• **Reports**
  • Released to SPHL electronically
  • CDC can release to originalsubmitter for urgent patient care purposes and will communicate with SPHL concurrently
Highlighted test systems
Morphological Identification

• Test codes
  • Parasites: Morphological identification (CDC-10234)
  • Malaria: Morphological identification (CDC-10520)

• Physical specimens – consult with lab for specific conditions (preapproval)
  • Whole blood
  • Stool*
  • Other fluids*
  • Whole organisms*
  • Slides

*(in preservative/fixative)
Chagas disease

Thanks to Dr. Herb Tanowitz
Chagas disease testing

• **Molecular detection**
  - Test code CDC-10475 (Chagas disease molecular detection)
  - Request preapproval to determine if test request is appropriate for case (acute phase)
  - Specimens: Whole blood (EDTA), CSF, unpreserved heart tissue
  - Methodology
    - Real-time PCR to two *T. cruzi* targets

• **Serology**
  - Test code CDC-10458 (Chagas disease serology)
  - Request preapproval to determine if test request is appropriate for case (chronic phase)
  - Confirmation requires two or more serologic tests using different antigens
  - Specimen: serum
  - Methodology
    - EIA, Immunoblot
    - May request 2nd specimen if divergent
    - Repeat EIA, immunoblot
    - If still divergent; IFA
Leishmania species identification

• Test code: CDC-10238
• Preapproval required
• Specimens
  • EDTA-treated blood, bone marrow
  • Unpreserved skin tissue (in sterile buffered medium)
• Methodology
  • Real-time PCR targeting ITS2 to detect *Leishmania* spp.
  • Sequencing to identify species

• Formalin-fixed tissue specimens
  • May be submitted to Infectious Disease Pathology Branch with Test Order CDC-10365 (Pathologic Evaluation of Tissues for Possible Infectious Etiologies)
  • Extracted DNA may be used in Leishmania species identification test
  • May be difficult to resolve species with this specimen type
Trichomonas Susceptibility

- Test code: CDC-10239
- Request preapproval; CDC can provide InPouch TV
- Specimen is an inoculated InPouch TV
- Must arrive at CDC within 48 hours of collection at ambient conditions (18-25°C)
- Isolate is recovered in culture medium
- Microplate dilution of antimicrobials (metronidazole, tinidazole) to generate Minimum Lethal Concentration
Modernizing the diagnostic laboratory
Need for improved tests

• Why do we need improved tests?
  • Improved performance, accuracy
  • Sustainability of reagents
  • Adaptability to changing needs, updated equipment, new targets

• Actions
  • Designing new laboratory developed tests
  • Engage partners with new methods, test systems
  • Develop specimen panels to conduct validations

https://www.cdc.gov/parasites/lab_science.html
• NGS-based method
• Enrich parasite DNA extracted from specimens
• Conduct deep sequencing of parasite target (e.g. 18S rRNA)
• Dedicated bioinformatics pipeline using reference sequence database
Multiplex Bead Array

- Utilize recombinant antigens to design assays using Luminex instruments
- Allows multiplexing of antigens (e.g. multiple species-specific antigens)
- Increased throughput
- Standardize methodologies and reagents used in serological analysis
How to contact us

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.