

OnSite™

rK39 + rK28



Simple Accurate Diagnosis of Visceral Leishmaniasis

CTK Offers Rapid Tests to quickly aid in diagnosis of infection with *L. donovani* complex using patented rK39 & rK28 antigens to ensure accurate results in spite of geographic variation

Visceral leishmaniasis (or Kala-azar), found in tropical and subtropical areas of all continents except Australia, affects 12 million people with an additional 1-2 million new cases per year. Leishmaniasis is transmitted by the female sandfly carrying *Leishmania donovani* complex parasites which if left untreated may result in death.

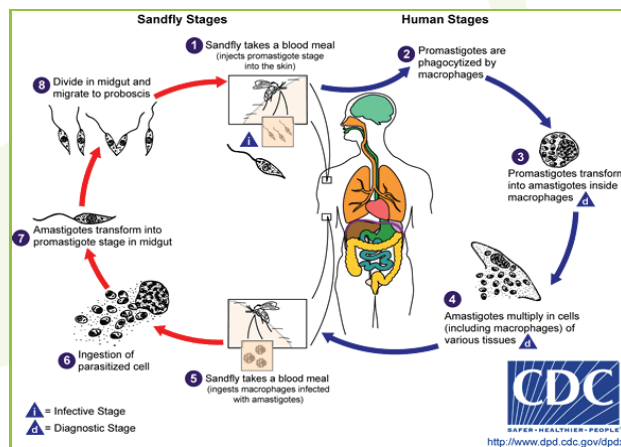
Visceral leishmaniasis can be diagnosed via:

- Microscopy to directly identify parasites
- Culture to directly identify parasites
- Serological test for the presence of IgG and IgM antibodies against parasites

CTK Offers Rapid Tests to aid in the diagnosis of Visceral Leishmaniasis. In addition to rK39, these kits utilize a newly licensed antigen, rK28, to minimize geographic variation:

- The **OnSite** Leishmania IgG/IgM Rapid Test (Catalog #R0121C) differentiates IgG and IgM antibodies to *L. donovani* complex in plasma, serum or whole blood.
- The **OnSite** Leishmania Ab Rapid Test (Catalog # R0121S) detects antibodies (IgG/IgM) to *L. donovani* complex in plasma or serum. Strip format is cost effective.

L. donovani parasite life cycle



OnSite Rapid Tests for instant detection of leishmania infection

Catalog	Product	Detection	Samples	Test Time
R0121C	Leishmania IgG/IgM Combo Rapid Test CE	3 line test differentiates IgG and IgM to <i>L. donovani</i> complex	Serum, plasma & whole blood	15 min
R0122S	Leishmania Ab Rapid Test CE	2 line test detects antibodies (IgG and IgM) to <i>L. donovani</i> complex	Serum, plasma	15 min



Visceral Leishmaniasis Diagnostics at a Glance

Methods		Specimens	Test time	Remarks
Microscopy		Splenic aspirate, bone marrow biopsy	≥ 1 hour	<ul style="list-style-type: none"> Invasive procedure to obtain specimen, potentially life-threatening Requires skilled technician for sampling and Testing
Culture		Splenic aspirate, bone marrow biopsy	10-21 days	<ul style="list-style-type: none"> Invasive procedure to obtain specimen, but can be dangerous Technically difficult, require steril culture setting
Serodiagnosis (Detects Ab)	DAT*	Serum, plasma	Over night	<ul style="list-style-type: none"> Need microtitration plates and incubator Dilute specimens prior to assaying
	IFA**	Serum, plasma	≥ 1 hour	<ul style="list-style-type: none"> Dilute specimen prior to assaying Requires fluorescence microscope Cross reacts with trypanosoma cruzi
	ELISA	Serum, plasma	≥ 1 hour	<ul style="list-style-type: none"> Trained technician Requires incubator and ELISA reader
	Rapid test	Serum, plasma, whole blood	15 minutes	<ul style="list-style-type: none"> No equipment required Minimal training Irrespective of parasite stage <p>A simple and accurate test</p>

*DAT: Direct Agglutination test

** IFA: Immunofluorescence Assay

OnSite Leishmania Rapid Test Kit Performance

1. Clinical Study

Product	Catalog	Samples	Sensitivity	Specificity	Reference
OnSite Leishmania IgG/IgM Combo Rapid Test CE	R0121C	234	91.2%	99.5%	ELISA
OnSite Leishmania Ab Strip Test CE	R0122S	200	100%	100%	Rapid Test

2. WHO Evaluation (Visceral leishmaniasis rapid diagnostic test performance, Diagnostics evaluation series No.4, Aug, 2011)

Parameter	OnSite R0122S	Participant A	Participant B	Participant C	Participant D
Sensitivity (n=250)	99.6% (97.8 -99.9%)	92.8% (88.9 -95.4%)	98.8% (96.5 -99.6%)	99.6% (97.8 -99.9%)	100% (97.9 -100%)
Specificity (n=249)	96.8% (93.8 -98.4%)	99.2% (97.1 -99.8%)	97.6% (94.8 -98.9%)	96.0% (92.8 -97.8%)	100% (97.8 -100%)
Average Score (Highest 18)	13.5	9.9	11.0	11.8	10.9

