The Role of RDTs in Improving the Clinical Management of Patients Presenting with Intestinal Disorders

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Mali

nidiag

Better Diagnosis of Neglected Infectious Diseases

INSTITUT NATIONAL DE RECHERCHE EN SANTE PUBLIQUE

MALI

I.N.R.S.P.

Research Team in Mali

- Pr. Mamadou S. Traoré (Director)
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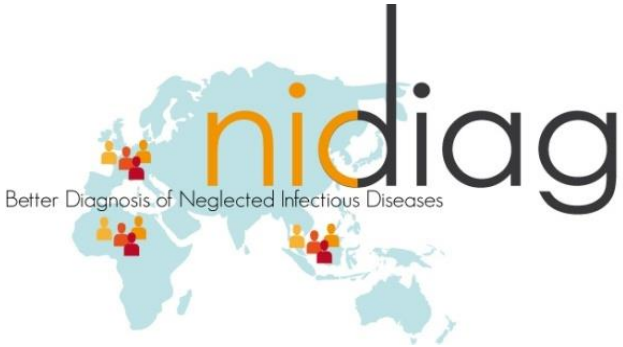
- Dr Keita Mama Doumbia
- Hassane Fofana
- Seydou Diarra

- Regional Health Director (Ségou)
- Medical Distric Officer (Niono)
- Clinicians (Niono District Health Centre)
- Lab Technicians (Niono Distrit Health Centre)

NIDIAG

Study title:

Diagnosis of neglected tropical diseases among patients with persistent digestive disorders: a multi-country, prospective, non-experimental case-control study



Objectives

- **To improve the quality of clinical care for persistent diarrhoea and persistent abdominal pain through the development of evidence-based diagnosis-treatment algorithms for use in primary health care centres**

- **To identify the major NTDs and other infectious agents (i.e. bacteria and parasites) that give rise to persistent digestive disorders and to assess their relative contribution to this clinical syndrome**

- **To compare different diagnostic methods and to assess their diagnostic accuracy, including clinical features, conventional laboratory techniques, recently developed rapid diagnostic tests (RDTs) and molecular assays for the diagnosis of selected pathogens**

- **To assess the clinical response to commonly employed empiric treatment options for persistent digestive disorders**

Intestinal disorders pathogens

- Bacteria
- Viruses
- Parasites

- Acute disease
  - Mainly bacteria and viruses
- Chronic disease
  - Parasites

- The diagnosis of major parasitic infection is not performed properly before beginning the treatment

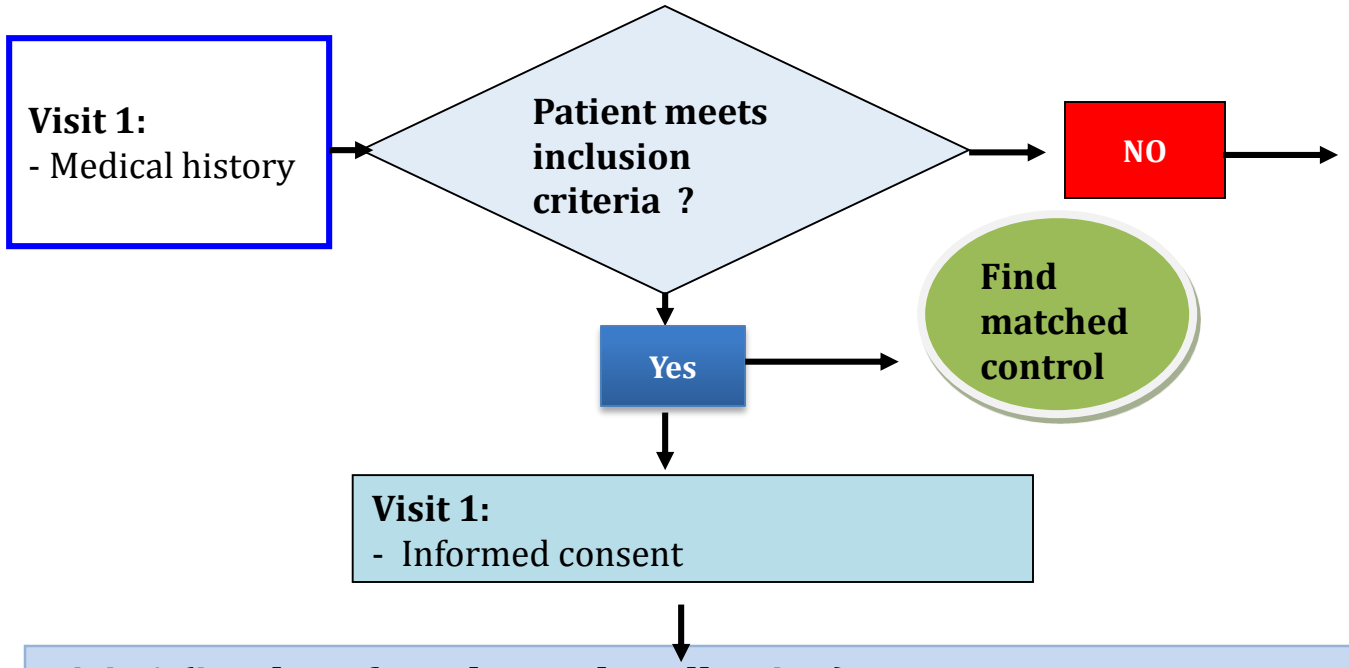
- Microscopic examination is still the method of choice to detect parasite on stool and urine.

Microscopy on stool samples

Microscopic diagnosis is the established gold standard for detecting and confirmation of an active parasitological infection

- Direct smear
- Classic Concentration Techniques
  - Kato Katz
  - Formol Ether Concentration
  - Baerrman Concentration technique
- Mini-FLOTAC
- Staining technique

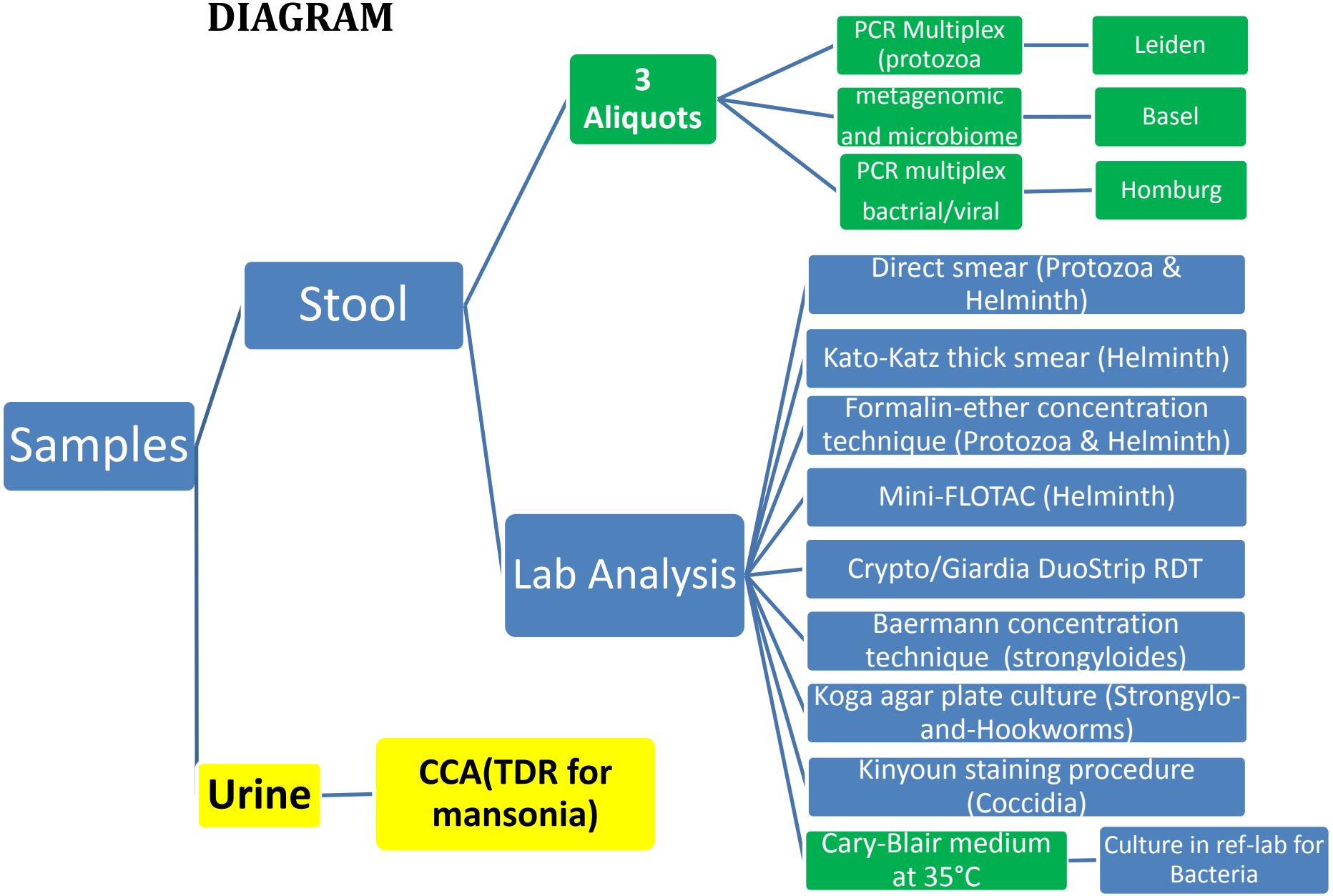
Study Flowchart : syndrome of persistent digestive disorders



Visit 1 (i.e. day of stool sample collection):

1. History taking (demographic, epidemiological, and clinical history)
2. Full clinical assessment, including nutritional status: anthropometric dimensions, clinical signs of malnutrition
3. Stool sample collection: Stool culture on selected media (pathogenic bacteria), Baermann concentration (*Strongyloides stercoralis);* Microscopy on stool samples: direct examination, concentration techniques, double Kato-Katz thick smear, mini-FLOTAC (intestinal protozoa and helminths); Crypto/Giardia Duo Strip for *Cryptosporidium spp., Giardia intestinalis;* Stool preservation (e.g. SAF, ethanol, freezing) for shipment and further investigations (retrospective analyses and PCR)
4. Urine sample collection: Urine CCA cassette test for *Schistosoma mansoni*
5. Other tests (e.g. HIV): according to routine country standards
6. Treatment (according to routine country standards):

SAMPLES MANAGEMENT DIAGRAM



Why RDT??

- Microscopic diagnosis is the established gold standard for detecting and confirmation of an active parasitological infection

- However, microscopic diagnosis are often not available at the district health centers and remote areas
  - Laboratory at he peripheral not well equipped
  - Accuracy of the results questionable
  - Lack of qualified human resources
  - Inappropriate diagnosis and treatment

CCA Kit

Crypto-Giardia Duo test

RDT for Schistosomiasis and Crypto-Giardia

- **The urine CCA** (Circulating Cathodic Antigen) cassette test for the qualitative presumptive detection of an active *Schistosoma* infection

- Crypto-Giardia Duo test
  - detection of both *Giardia lamblia* (syn.: *Giardia intestinalis*) and *Cryptosporidium* spp. in stool specimens.
  - This device consists of a two-sided stick (similar to two separated sticks which would be placed back to back) each side specific either for *Cryptosporidium* or for *Giardia lamblia*

CCA Assay procedure

Ensure all reagents are equilibrated to room temperature (20-25°C) before commencing the assay.

•Squeeze the pipette bulb and insert the tip into the urine sample.

•Allow the sample to fill up by gently releasing the bulb

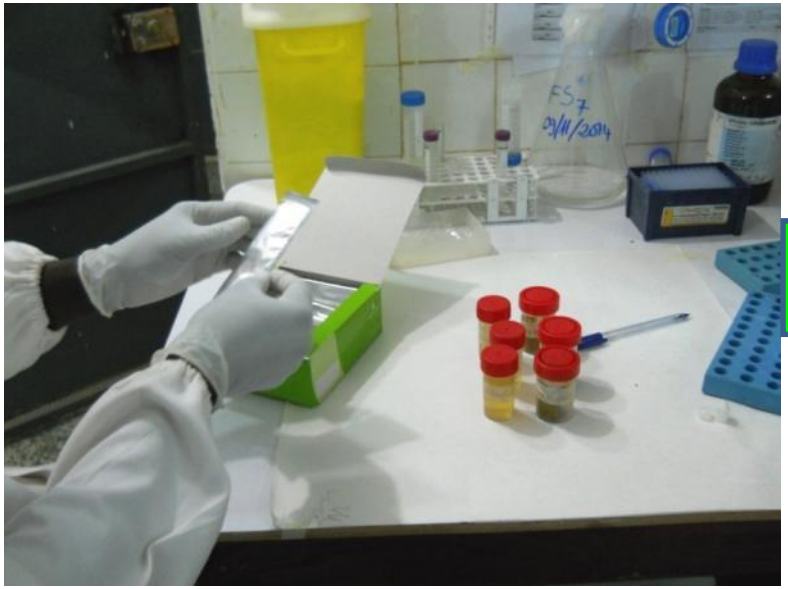
•Transfer 1 drop of urine to the circular well of test cassette by gently squeezing the bulb.

•Allow the sample to absorb entirely into the specimen pad within the circular well.

Hold the Buffer bottle vertically and 1cm above the circular well.

Add 1 drop of Buffer

Read the result exactly **20 minutes** after adding Buffer to the test Cassette.

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INTERPRETATION OF RESULTS:

POSITIVE

Control band turns pink.
A band is present in the test T area.
The test is positive for Bilharzia.

NEGATIVE

Control band turns pink.
No test T band present.
Demonstrates the test was performed correctly but no Bilharzia antigens were detected.

INVALID

Control line stays blue.
Only a pink control line should be considered positive.
The test is invalid and should be repeated.

A test line with no control line.
A pink control line must be present.

Comment

- POC-CCA is an antigen detecting test which is present in all Schistosoma species (we are testing just for the mansoni by microscopy)

- Levels in urinary schistosomiasis are variable, and also seem to differ between regions.

- The limit of detection by the CCA urine is comparable to the limit of detection by egg counts.


Crypto/Giardia
Duo-Strip
CORIS
Cryptosporidium & Giardia Diagnostic
Crypto/Giardia
Duo-Strip
Rapid Diagnostic Test
for Cryptosporidium
and Giardia Detection
in Stool Specimens
- Σ 25 -
Crypto/Giardia
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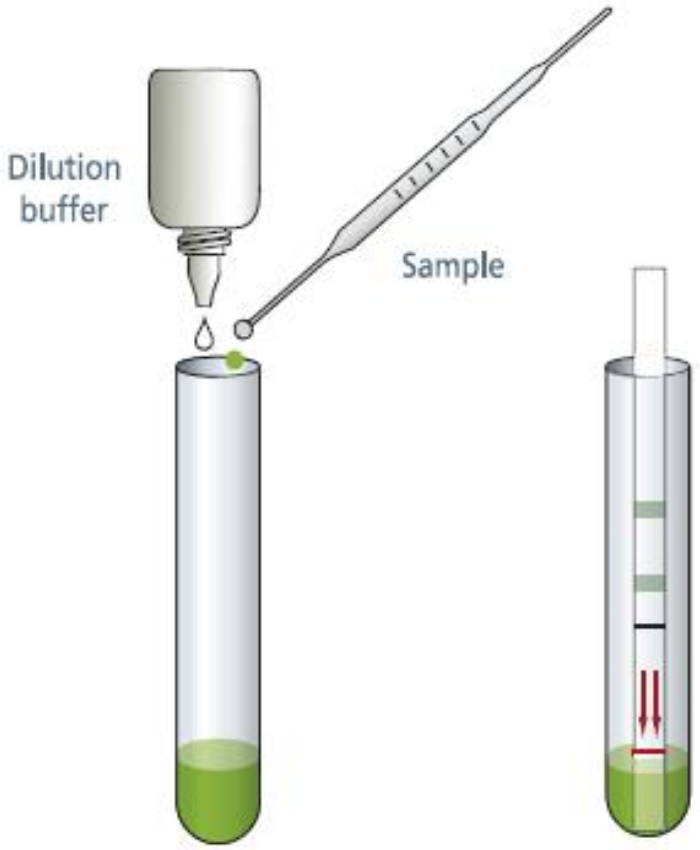
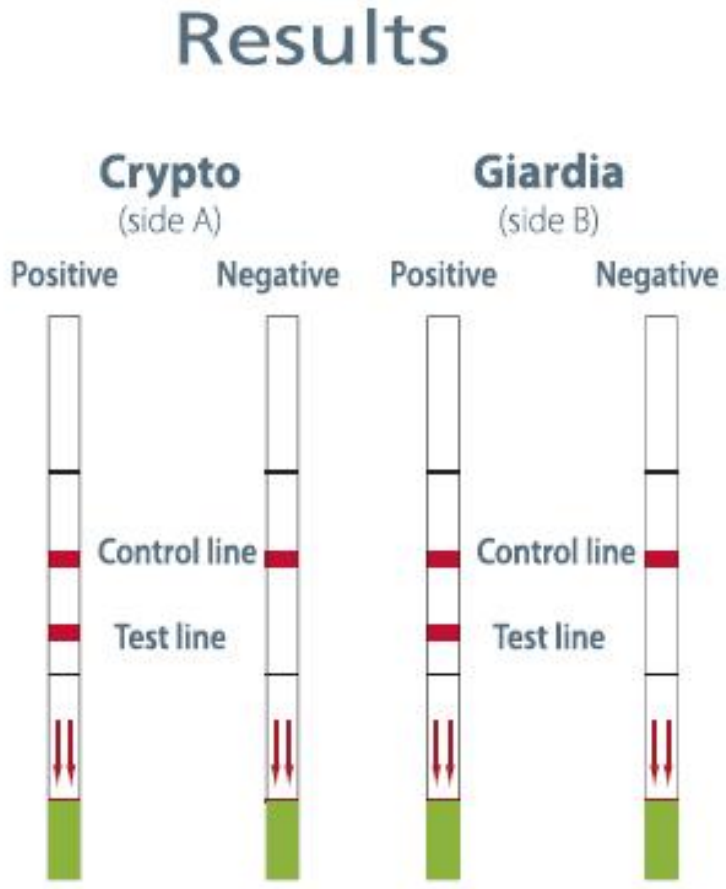
Crypto-Giardia Procedure summary





Crypto-Giardia Duo test for Giardia
Tested in Mali (Niono District Health Centre) under NIDIAG Project (August-November 2014)

Crypto-Giardia RDT	Microscopie/Ritchie		Total
	Positive	Negative	
Positive	78	4	82
Negative	5	195	200
Total	83	199	282

Se = 94.0% Sp=98.0% ; CO = 96.8 %

Urine CCA test for *S. mansoni*
Tested in Mali (Niono District Health Centre) under NIDIAG Project (August –November 2014)

CCA RDT	Microscopie/Kato Katz		Total
	Positive	Negative	
Positive	146	36	182
Negative	0	99	99
Total	146	135	281

Se = 100% Sp=73.3% ; CO = 87.2%

41 cases have Low band (+/-)

Stool examination at the Health Centre

From January to August In 2014

- Only 30 stools examination at the Niono District Health Centres were performed compared 282 for NIDIAG in 3 months
  - Direct smear microscopy
- 13 samples found positive
  - *S mansoni* = 4
  - *E histolitica* = 5
  - *Tenia = 1*
  - *Trichomonas = 4*

    1 mixed infection S.m+E.h

Case Management

- **RDT comprable to microscopy**
- **Right diagnostic**
- **Rapid intervention**
- **Apropriate treatment**


THANK YOU