Material Request Form

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

WHO/HAT/Specimen bank

WHO-IDM

For administrative use

MATERIAL REQUEST FORM

WHO

Human African Trypanosomiasis

SPECIMEN BANK

A. Requesting Party	Team Aberdeen iGEM2014
B. Contacts ③ **Name of the contact person** ③ **Shipping Address** ③ **E-mail address** ③ **Tel** ③ **Fax**	James McAvoy 2:054 Polwarth Building Foresterhill Aberdeen AB25 2ZD James.mcavoy.12@aberdeen.ac.uk +44 (0)1224 437300

C. Specimens Requested: Please indicate the appropriate number (and volume) of samples requested by type and class

Sample type	Standard Volume of each aliquot	Indicate volumes of aliquots if standards are not adequate	Number of samples required									
			PG1	**PG2**	**CG**	**S1***	**S2***	**S3***	**S4***	**SF***	**PR1**	**PR2**	**CR**
Serum	200 µl		30		6	(6)	(6)	(6)	(6)	(6)			
Plasma (on heparin)	200 µl												
Buffy coat (♦)													
Urine	500 µl												
Saliva	200 µl												
CSF	200 µl												
CSF Sediment (♦)													

(♦) Buffycoat and CSF sediment are not aliquoted. The whole original cryotube is sent.

Code	Diagnosis	Parasite or area of concern	Stage	Complete labeling
PG1	**Patient**	**T.*b. gambiense***	**1**	**Patient / T.*b. gambiense* / 1st stage**
PG2	Patient	T.*b. gambiense*	2	Patient / T.*b. gambiense* / 2nd stage
PR1	Patient	T.*b. rhodesiense*	1	Patient / T.*b. rhodesiense* / 1st stage
PR2	Patient	T.*b. rhodesiense*	2	Patient / T.*b. rhodesiense* / 2nd stage
CG	**Control**	**Area of T.*b. gambiense***	**NA**	**Control / area of T.*b. gambiense***
CR	Control	Area of T.*b. rhodesiense*	NA	Control / area of T.*b. rhodesiense*
SX(1 to F*)	**Suspects**	**Area of T.b. gambiense**	**NA**	**Suspects X (1 to F*)**
(*) For the suspects, S1 means the initial examination, S2 the second examination… and SF the final available examination				

If there are any special requirements on sample storage or other parameters, please indicate here:

Please do not mix aliquots from different patients, they must remain separate, and please label each with an identifier code. If known please state the antigen presentation or level of active immune response in the infected patients (i.e. volume of buffy coat, patient symptoms).

The control groups must be from from patients that have not previously suffered from *T.b. gambiense* infection, and are immune naïve.

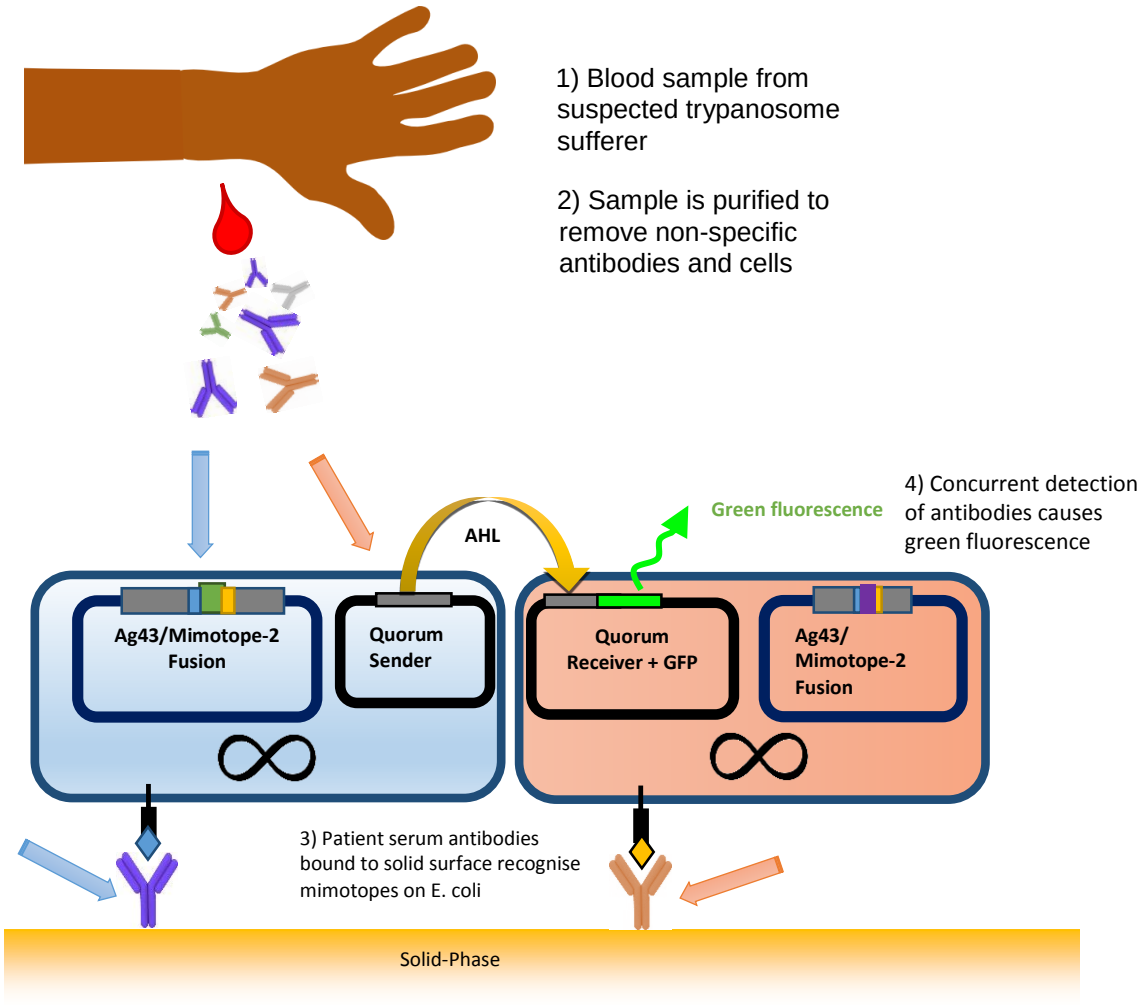
D. Specimens from the WHO HAT Specimen Bank are intended only for use in research, development, testing and/or evaluation of new HAT diagnostics, which are appropriate for use and affordable in developing countries, hereinafter referred to as "the Research, Development, Testing and/or Evaluation".

Describe the Research, Development, Testing and/or Evaluation for which you are requesting Clinical Specimens (give details and continue on a separate sheet, if necessary). Please reference any previously published or abstracted information concerning this assay:

We are designing an *E. coli*-based system for the diagnosis of Human African Trypanosomiasis. To ensure its effectiveness we need to test it using real patient serum samples.

The *E. coli* will express Antigen-43 and Ice Nucleation Protein constructs on the cell surface, that carry an additional sequence of amino acids called a 'mimotope'. The mimotope (mimic epitope), functions as a target for trypanosome-specific antibodies in the blood, which may be present. If these antibodies exist they will be detected by the *E. coli*.

To ensure effectiveness across a range of antigen-presentations we need to obtain samples from active immune responses to a range antigens present during stage 1 *T.b. gambiense,* therefore we would require samples from each patient at a range of time points due to antigenic variation.



Advantages

Existing biochemical diagnostics rely on costly antibodies, these need to be stored at sub-zero temperatures and are quickly denatured otherwise.

In contrast, this system is very inexpensive, requiring simple antibiotic media. It is unique in that it is capable of detecting the concurrent presence of 2 markers, and when performed in an array it could test for multiple trypanosome antigen subtypes.

The system would be heat tolerant, actively growing in conditions up to 37˚C, and could survive temperatures up to 60˚C. This will enable diagnosis where there are minimal facilities available.

Submissions

The results for this experiment would contribute to a final submission for review by the iGEM 2014 committee, and 'experience' section of the iGEM BioBrick respository (http://parts.igem.org/Main_Page) in proving the effectiveness of the diagnostic method.
iGEM is a multinational competition for undergraduate students developing novel synthetic biological systems for a wide range of uses, including disease diagnosis.
There is no need for information other than antibody distribution, disease presentation, and geographical origin.
Data will be stripped of all identifiable information of the patient.

E. The Specimens (hereinafter referred to as "the Material") and any information relating thereto (hereinafter referred to as "the Information") are provided on the following conditions:

1. The entity requesting and receiving the Material and the Information, hereinafter referred to as "the Receiving Party", will not permit the Material and/or the Information, or any part thereof, to come into the possession or control of any other entity or person, except those who are engaged in the above-mentioned Research, Development, Testing and/or Evaluation, under the supervision of the Receiving Party and who have accepted the same obligations in respect of the Material and the Information as set forth in this document.

2. The Receiving Party will use the Material and the Information exclusively for the purpose of the Research, Development, Testing and/or Evaluation of Human African Trypanosomiasis (HAT) diagnostics tests described under section D. Without the prior written authorization of WHO, the Receiving Party will not sell, or have sold, furnish or have furnished, such Material and/or Information to any third party. Except as explicitly provided in this Material Request Form (including Section D above), the Receiving Party will not, furthermore, use, or have used, such Material and/or Information in any way for the commercial production or sale of any products, or otherwise for commercial purposes.

3. Other than explicitly provided herein, this Material Request Form will not be construed as conveying to the Receiving Party any rights or title to the Material and/or the Information. The Receiving Party will treat the Material and Information as strictly confidential and proprietary to WHO, and/or persons or entities collaborating with WHO, and will disclose such Material and Information only under the same obligations of confidentiality and restrictions on use as those contained herein.

   Obligations of confidentiality will not apply to Information which the Receiving Party can show was in the public domain at the time of its acquisition hereunder, or becomes part of the public domain otherwise than by breach of the undertakings set forth in this Material Request Form.

4. The Material is not appropriate, nor intended, for use in humans.

5. WHO and persons and entities collaborating with WHO make no warranty of merchantability or fitness of the Material or the Information for any particular purpose or any other warranty, either express or implied.

The Receiving Party agrees that WHO has no control over the use that is made of the Material and the Information by the Receiving Party. Consequently, the Receiving Party agrees that WHO shall not be liable for such use.

Thus, the Receiving Party agrees to assume full responsibility for, and to hold WHO harmless from, any and all claims and liabilities resulting from or otherwise related to, the possession and use of the Material and/or the Information, as well as of materials incorporating the Material.

6. The Receiving Party will ensure that the Material will at all times be used and handled in compliance with all relevant laws, rules and regulations applicable to the use of biological materials. The Receiving Party furthermore undertakes to comply with the **Transport of Infectious Substances, WHO/CDS/EPR/2007.2.** Upon the Receiving Party's request, WHO will provide the Receiving Party with a copy of these Guidelines.

7. Any information provided by the Receiving Party to WHO under, or in connection with, this Material Request Form, will - if marked 'confidential' - be treated by WHO as confidential and proprietary to the Receiving Party, for a period of five years after the disclosure of such information to WHO. In this connection, WHO will only use and disclose such information (under similar obligations of confidentiality and restrictions on use as those contained herein) for the purpose of evaluating such information and determining (in WHO's sole discretion) the merit of releasing Material for Research, Development, Testing - and/or Evaluation - activities by the Receiving Party.

   However, there will be no obligations of confidentiality and restrictions on use, to the extent that WHO is clearly able to demonstrate that the aforementioned information or any part thereof:

   I. was known to WHO prior to their disclosure by the Receiving Party hereunder; or

   II. has been independently devised, or arrived at, by WHO without access to the disclosure made by the Receiving Party hereunder; or

   III. was in the public domain at the time of disclosure hereunder, or becomes part of the public domain through no fault of WHO; or

   IV. becomes available to WHO from a third party, who is not in breach of any obligations of confidentiality owed to the Receiving Party

8. Prior to publication or presentation of any results using the Material and/or Information, the Receiving Party will provide WHO with a copy of such intended publication or presentation for the purposes of ensuring that it contains no disclosure of confidential and/or proprietary Information. Any objection to publication or presentation for the aforesaid reason will be notified by WHO to the Receiving Party within a period of sixty days of receipt of the draft copy. In the absence of such an objection within that sixty-day period, the publication or presentation may proceed. All such intended publications and presentations will contain an acknowledgement of WHO, the WHO HAT Specimen Bank, the Collection Sites and the Repository. The Receiving Party agrees to consult WHO with regard to giving appropriate acknowledgement as aforesaid, before such publication is published or presentation is made.

9. On completion of the Research, Development, Testing and/or Evaluation, the Receiving Party shall notify the result of the use of the Materials and/or Information to WHO.

10. The Receiving Party shall notify WHO in writing of any invention, improvement, modification, discovery or development made by the Receiving Party with respect to the Material and/or Information. The Receiving Party furthermore agrees that WHO and parties collaborating with WHO shall in any event entitled to receive samples of any material derived from the Material for their own research and evaluation purposes.

11. The Receiving Party will ensure that any product resulting from the use of the Materials and/or Information will be safe and effective and manufactured in accordance with Good Manufacturing Practices.

12. The Receiving Party will ensure that the commercial exploitation of any product resulting from the use of the Material will be designed to achieve the following objectives in the following order of priority:

    (a) the general availability of the product

    (b) the availability of the product to the public health sector in developing countries on preferential terms.

In connection with the foregoing the Receiving Party will ensure that the product will be made available at cost to the public sector in developing countries that have reported probable HAT cases to WHO.

On the request of WHO, the Receiving Party will present supporting documentation adequately justifying the proposed pricing structure.

13. On completion of the Research, Development, Testing and/or Evaluation, using the Material, the Receiving Party will cease to use any remaining quantities of the Material and the Information for any purpose and, at the direction of WHO, either destroy, or return to the Repository, all such remaining quantities of the Material and any and all copies of the Information. 14. Completion of the Research, Development, Testing and/or Evaluation, using the Material will not relieve the Receiving Party of any obligations under this Material Request Form.

15. Without the prior written consent of the other party, neither party will, in any statement, or material of an advertising or promotional nature refer to the relationship of the other party to their collaboration pursuant to this Material Request Form, or to the relationship of the other party to the Materials, Information or any product resulting from their use.

    Any dispute relating to the interpretation or application of this Agreement will, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute will be settled by arbitration. The arbitration will be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties will accept the arbitral award as final.

    If the foregoing terms and conditions are acceptable, please complete and return this document to the address mentioned below. Please note, however, that your signature of this document does not automatically imply that you will receive the Material and the Information, nor that you will receive the materials in the quantity requested by you. Once your request has been approved by WHO, arrangements will be made for dispatch of the Material to you (of which arrangements you will be notified). You may wish to take a photocopy of this form for your records.

I certify that I have read and I accept the conditions listed above:

Signature of Receiving Party:	Date:
Name of Receiving Party:	
Title of Receiving Party:	
Name of Institute:	

I warrant that I, as the Responsible Administrative Authority of the Receiving Party have the full authority to execute this Agreement and to thereby bind the Receiving Party:

Signature of the Responsible Administrative Authority:

Please return this form (**two** copies with original signatures) to: **Dr Pere SIMARRO,**
Innovative and Intensified Disease Management,
NTD / IDM,
World Health Organization,
1211 Geneva 27, Switzerland.
FAX: +41 22 791 4777 Approved

by WHO:

Sample type	**Volume of each aliquot**	**Other volumes**	**Number of samples approved**										
			PG1	**PG2**	**CG**	**S1**	**S2**	**S3**	**S4**	**SF**	**PR1**	**PR2**	**CR**
Serum	200 µl												
Plasma	200 µl												
Buffy coat (♦)													
Urine	500 µl												
Saliva	200 µl												
CSF	200 µl												
CSF Sediment (♦)													

(♦) Buffycoat and CSF sediment are not aliquoted. The whole original cryotube is sent.

Comments

Signature:
Name:
Title:
Date:

Material Release Form for Repository

WORLD HEALTH ORGANIZATION / ORGANISATION MONDIALE DE LA SANTE / NTD-IDM **WHO/HAT/Specimen bank**

A. Requesting Party	
B. Contacts ③ **Name of the contact person** ③ **Shipping Address** ③ **E-mail address** ③ **Tel** ③ **Fax**	

Sample type	**Volume of each aliquot**	**Volumes of aliquots if standards are not adequate**	**Number of samples released**									
			PG1	**PG2**	**CG**	**S1***	**S2***	**S3***	**S4***	**SF***	**PR1**	**PR2**	**CR**
Serum	200 µl												
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CSF Sediment (♦)													

(♦) Buffycoat and CSF sediment are not aliquoted. The whole original cryotube is sent.

Comments:

WHO

Signature:
Name:
Title:
Date: