Annual Review of Risk Assessment Made Under:
Control of Substances Hazardous to Health Regulations

WORK WITH BIOLOGICAL MATERIAL

Department: Nuffield Division of Clinical Laboratory Sciences
Radcliffe Department of Medicine

Supervisor: Dr Monique Andersson

Ref No: NDCLS-RA-024

Title: Sexually Transmitted infections in diagnostic Evaluation using Point of care isothermal amplification (STEP)

The Risk Assessment has been reviewed: ..... YES
Key aspects*: Persons involved, source organisms, hazard group, co-pathogens, identification of any potentially harmful effects, consequences of infection, routes of infection, control measures, and disposal of waste.*

Appropriate containment measures have been confirmed:..... YES

Original containment level and risk classification remain valid:... YES

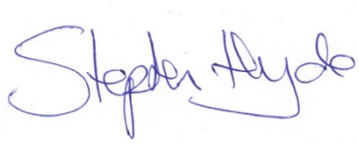
Classification and assignment of final control measures:

Containment Level: ..... CL 2

What has changed? Updated list of users

Reviewed By:
Date (YYYY-MM-DD):
Dr Monique Andersson
2025-10-22

Approved By Divisional Safety Advisory Committee
Agreed By One-Of DSO/BSO:
Date (YYYY-MM-DD):
Prof Stephen Hyde – NDCLS BSO
2025-10-29



Approved by Head of Department
Date (YYYY-MM-DD):
Prof Deborah Gill – NDCLS HoD
2025-10-29

Next Review Due: Before end 2026

Risk Assessment Users & Supervisor During Previous Year
Monique Andersson
Johnny Zhou (M. Andersson)
Sophie Ramage (M. Andersson)

Risk assessment made under the
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WORK WITH MICRO-ORGANISMS

This form is to be used to identify the handling precautions to be adopted for each different micro-organism (including cell lines) used whether pathogenic or not. Please refer to Policy statement S5/09 for full assistance in completing this form. Once completed please return to the Departmental Biological Safety Officer for approval **before** receiving the micro-organism. New micro-organisms must be notified to the University Biological Safety Officer prior to work commencing.

If the organism has been genetically modified previously or is going to be genetically modified a specific risk assessment is required under the Genetically Modified Organisms (Contained Use) Regulations.

If the organism is to be obtained from outside the UK or its use is otherwise controlled by DEFRA then licences should be obtained as appropriate.

If the micro-organism is to be administered to laboratory animals an Animal Care Workers Risk Assessment must be undertaken (see Policy statement S5/09). Any persons handling the micro-organism who might have compromised resistance to disease for any reason should seek further advice regarding the need for additional precautions from the University Occupational Health Physician.

TITLE OF PROJECT: Sexually Transmitted infections diagnostic Evaluation using Point of care isothermal amplification (STEP)
OVERVIEW OF PROJECT: To determine the performance of a point of care LAMP (Loop-Mediated Isothermal Amplification) test for Neisseria gonorrhoeae (NG), Chlamydia trachomatis (CT), Trichomonas vaginalis (TV), Herpes Simplex Virus (HSV) in vaginal swab, throat swab, rectal swab and first void urine (FVU) or ulcer/vesicle swab via fluorescence and lateral flow readout
LOCATION OF WORK: NDCLS Laboratory 5501, John Radcliffe Hospital

Supervisor (PRINT): MI Andersson **Signature:**  **Date: 17.04.2023**	**Assessed by (if not Supervisor) (PRINT):** **Signature:** **Date:**
Work approved by **(Biological) Safety Committee: YES / ~~NO~~** **Biological Safety Officer: Prof Steve Hyde**  **Signature:** **Date: 24 May 2024**	**Permission granted by HoD** **for work to commence (if required): YES / ~~NO~~** **Head of Department: Prof Deborah Gill**  **Signature:** **Date: 24 May 2024**
Persons involved: MoniqueAndersson Johnny Zhou	

FULL NAME OF ORGANISM: **Including species, subspecies, strain**	*Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Trichomonas vaginalis*, Herpes Simplex Virus (HSV)
IS IT PATHOGENIC TO HUMANS?	YES
If pathogenic specify consequences of infection(s) (severity and type or illness caused):	*N gonorrhoeae* – conjunctivitis,pharyngitis (mild to moderate), *C trachomatis* conjunctivitis (mild to moderate), *T. vaginalis* conjunctivitis (mild), HSV - skin ulceration (mild to moderate)
ASSIGN ADCP HAZARD GROUP:	2
IS IT PATHOGENIC TO ANIMALS? **If pathogenic to animals please contact University Biological Safety officer for further advice as different licences may be required.**	NO
ASSIGN DEFRA HAZARD GROUP:	1 2 3 4
IS IT A SPECIFIED ANIMAL PATHOGEN?	NO
IS IT LISTED ON SCHEDULE 5 OF ANTI-TERRORISM CRIME AND SECURITY ACT?	NO
HAS THE ORGANISM BEEN ATTENUATED?	NO
NATURE OF ATTENUATION	
COULD A LESS HAZARDOUS ORGANISM BE USED?	NO
If yes, why not use it ?	The aim of the project is to develop an isothermal assay for rapid detection of STIs, so we must use the microorganism to establish the assay.
ARE THERE ANY OTHER HAZARDOUS PROPERTIES ASSOCIATED WITH THIS MICRO-ORGANISM?	NO
If yes identify type:	Toxic / Allergenic / Oncogenic / Carcinogenic / Other (specify)
ROUTES OF INFECTION:	**Ingestion (NG)** / Inhalation / **Percutaneous (HSV)** / **Ocular (NG, TV, CT and HSV)**

LABORATORY / EXPERIMENTAL PROCEDURES (typical volumes, frequency of use, etc.):

The reaction mixture (12.5 ul LAMP master mix + 2.5 ul 10X primers + 0.5 ul SYTO9 (25 uM) + 9 ul RNase/DNase Free water + 5 ul sample of interest including NG, CT, TV or HSV) will be mixed by pipetting each of these substances from their original container (a tube of maximum 1 mL volume) into PCR-tubes (0.2 mL volume). The PCR tubes will be placed in a heat block/qPCR machine (temperature: 65 °C) for 30 min for a fluorescent readout, followed by incubation at 95°C for 5 min to inactivate the enzyme. The experiment will be performed 1-2 times per week. After cooling back to room temperature, the PCR tubes will be then discarded as biological waste to be further autoclaved. All the surfaces will be cleaned by wiping out with 70% ethanol.

CONTROL MEASURES:

Containment Level:	2
Additional precautions:	
- Gloves	YES
- Avoid use of sharps	YES
- Use microbiological safety cabinet for aerosols	YES
- All material to be handled in microbiological safety cabinet	YES
- centrifugation	YES
- FACS (specify analysis / sorting)	NO
- Vortexing	YES
- Sonication	NO
- any other processes that generate aerosols	NO
- Other (specify)	n/a
- **Good microbiological practice:**	**YES**

MOST LIKELY & WORST CASE SCENARIO. INDICATE MITIGATING CONTROLS: (What could happen in extreme circumstances or is the most likely negative occurrence to happen)

The worst-case scenario would be a vial spill of bacteria or virus. As risk mitigating controls, all the bacteria/virus samples will be handled under the designated microbiological safety cabinet. If any such sample needed to be handled outside the safety cabinet in the general lab, it should be heat inactivated (at 95 °C for 10min) before opening the vial.

EMERGENCY SPILL PROCEDURES:

In the event of spillages, cover the spill with absorbent material soaked in disinfectant. Allow 10-30minutes. Clean the surface with 70% Ethanol. The contaminated absorbent material will be disposed in biohazardous waste and further autoclaved.

DISINFECTION PROCEDURES:

The safety cabinet will be cleaned with 70% ethanol and subjected to 20 min of UV irradiation before and after using the safety cabinet. Other working surfaces and equipment will be regularly cleaned with 70% ethanol and 1% Virkon spray to minimise DNA contamination and thus false positive signals. All laboratory procedures such as handling reagents or specimens will be performed while wearing protective equipment (laboratory coat, gloves and visor).

WASTE DISPOSAL PROCEDURES:

- All waste will be discarded into appropriate bins as instructed by the lab manager.
- All post-LAMP products must be carefully discarded to avoid contamination of the environment.
- Disposables (tips, gloves, Eppendorf tubes) will be disposed in biohazardous waste and autoclaved.
- 70% Ethanol should be allowed to evaporate from surfaces

STORAGE: State where micro-organism will be stored and if containment levels 2 and 3 apply.

No material will be stored in the NDCLS.

ADDITIONAL INFORMATION:

HEALTH SURVEILLANCE: ***hazard group 2 and 3 workers must register with the University Occupational Health Service using pathogen registration form***

VACCINATION(S):

Is an appropriate vaccination available?	NO
Can it be used in by experimenters?	**YES / NO**
Will it be offered?	**YES / NO**
If "no" why not?	