Target product profile
for a rapid, low-cost diagnostic to distinguish gonorrhoea from Chlamydia infection at primary care

FIND, Campus Biotech. Chemin des Mines 9, 1202 Geneva, Switzerland
T +41 (0)22 710 05 90, F +41 (0)22 710 05 99, www.finddx.org

Target product profile for a rapid, low-cost diagnostic to distinguish gonorrhoea from Chlamydia infection at primary care		
Characteristic	**Minimal**	**Optimal**
SCOPE		
1. Intended use	To detect Neisseria gonorrhoea (NG) only or NG and Chlamydia trachomatis (CT) infection to improve syndromic patient management and to facilitate appropriate antibiotic use	Same as minimum plus to assist in screening to identify previously undetected NG or NG and CT infections to support public health management
2. Target use setting	Primary health care settings including health posts (Level 1[1]); to be used after initial clinical evaluation (referring to Step 2 in the WHO Vaginal/Urethral Discharge Flowchart[2]) to guide treatment decision	
3. Test format / Equipment	A non-instrumented, single use, disposable diagnostic test preferred; Ideally no additional power required for operation, but if required, battery power with 8-hour operation between charges. Reader optional and only appropriate if its inclusion supports enhanced test performance (see Appendix 1 for reader requirements)	
4. Target users	The target users include community health workers with minimal training and any health worker with a similar or superior training level	
5. Target analytes	Identification of NG or NG and CT	Same as minimal, plus detection additional sexually transmitted infections (e.g. Mycoplasma and trichomonas) ideal
PERFORMANCE CHARACTERISTICS		

[1] Ghani AC, Burgess DH, Reynolds A, Rousseau C (2015). Expanding the role of diagnostic and prognostic tools for infectious diseases in resource-poor settings. *Nature* 528: S50-52

[2] https://apps.who.int/iris/bitstream/handle/10665/43275/9241593407_mod4_eng.pdf?sequence=5&isAllowed=y

6. Clinical Sensitivity[3]	>80% required to achieve the minimal intended use for a non-molecular test; >90% required to achieve the minimal intended use for a molecular test	>90% required to achieve the minimal intended use for a non-molecular test; >95% required to achieve the minimal intended use for a molecular test
7. Clinical Specificity[1]	>95% required to achieve the minimal intended use	>98% required to achieve the optimal intended use
8. Specimen[4]	Women: self-collected and provider-collected high vaginal swabs Men: urethral swab acceptable, urine preferred Same test format able to accept multiple specimen types to achieve results for men and women	Women: urine preferred, self-collected and provider-collected high vaginal swabs acceptable Men: urine, and rectal and pharyngeal swabs Same test format able to accept multiple specimen types to achieve results for men and women
9. Analytical Inclusivity	Assay detects geographically and genetically representative Neisseria gonorrhoea strains	
10. Analytical Exclusivity	No cross-reactivity with >95% of non-chlamydial and non-gonococcal pathogens and other microorganisms that frequently colonize and/or infect the genital tract especially non-gonorrhoeal Neisseria	No cross-reactivity with >99% of non-chlamydial and non-gonococcal pathogens and other microorganisms that frequently colonize and/or infect the genital tract especially non-gonorrhoeal Neisseria
OPERATIONAL CHARACTERISTICS		
11. Specimen preparation	Minimal sample processing; no more than one operator step	Integrated; no sample preparation required by user
12. Steps performed by healthcare worker between specimen preparation and result	No more than three operator steps, none of which is timed or labour intensive	One operator step (none of which has a timed interval), excluding waste disposal
13. Additional consumables required but not provided within the test kit	None, except for specimen collection	

[3] In genital specimens with performance verified as compared to nucleic acid reference standard

[4] Sensitivity and specificity for rectal and pharyngeal swabs is not yet determined

14. Cold chain	None required at any point	
15. Test kit	All materials required for test procedure, including devices, reagents or other consumables to diagnose one individual, included in packaged, self-contained kit (either packaged individually as one test per test kit or sufficient to perform the number of tests packaged in the test kit box – e.g. 20, 50 or 100 tests)	
16. Test kit stability and storage conditions	12 months, stable between 2-35°C, 70% humidity, 3000 meters altitude	18 months, stable between 0-50°C, 90% humidity, 3000 meters altitude
17. Environmental tolerance of packaged test kit	• Transport stress (48 hours with fluctuations up to 50 °C and down to 0 °C) • Tolerate exposures between 2 °C and 45 °C at an altitude up to 3000 meters, up to and including condensing humidity	
18. Operating conditions	• Operation between 15 °C and 40 °C at an altitude up to 2000 meters • Extremely low relative humidity to condensing humidity • Result interpretation in low light settings	Same, plus operation between 10 °C and 45 °C at an altitude up to 3000 meters preferred
19. Training required	< 90 minutes	30 minutes
20. Clean water	None required	
21. Time to result	≤30 minutes	≤10 minutes
22. Duration of sample stability (time from specimen collection to insertion into test cartridge)	Immediate testing of the sample	
23. Stability of valid result (read window)	At least 30 minutes (after which results may be *false* or *invalid*); Clear language in the instructions for use regarding test reading	≥1 hour (after which results give *invalid* rather than *false* results); Clear language in the instructions for use regarding test reading
24. Safety precautions (bio-safety requirements)	Closed, self-contained system; unprocessed sample transfer only; no open handling of biohazardous material	
25. Waste/disposal requirements	Standard biohazardous waste disposal or incineration of consumables, no high temperature incineration required	Small environmental footprint; recyclable or compostable plastics for test cartridges and other materials after decontamination, no incineration required

26. Internal QC - reagents	Procedural (reagent-addition) control internalized in cartridge for each individual test run; positive and/or negative control for internal QC available for purchase separately	Procedural (specimen-addition/sample adequacy) control internalized in cartridge for each individual test run; positive and/or negative control for internal QC provided in each box of test kits
27. Device control	Indicator of instability or expiration	Indicator of instability, expiration, inadequate sample and incorrect procedure and/or use but not as an additional component
28. Patient identification capability	Yes – simple, self-contained way to indicate a patient identifier	
29. Result display and interpretation	Result can be read with the naked eye with minimal instructions for interpretation required by user, or with an integrated reader (See Appendix 1) that supports enhanced test performance	
PRICING AND ACCESSIBILITY		
30. Target list price[5] per test (excluding the cost of a reader)	<$3 USD for a low complexity test (e.g. rapid diagnostic test) that meets the minimal intended use and clinical sensitivity and specificity TPP specifications; <$12 USD for a moderate/high complexity test (e.g. disposable single use molecular test) that meets the optimal intended use and clinical sensitivity and specificity TPP specifications	
31. Regulatory requirements	WHO PQ or other stringent regulatory body (e.g. FDA or CE mark)	

Appendix 1: Requirements for RDT reader (if required)

Adapted from RDT reader TPP prepared by the Murtagh Group, LLC (2014)

READER CHARACTERISTICS (if reader is required)	**Minimal**	**Optimal**
1. Ease of Use	No more than 3 operator steps (position RDT (cassette/strip) as required by the reader; take image or scan; read result); simple test menu; integrated LCD screen; simple key pad or touchscreen with icons	
2. Size	Small, portable table-top or hand-held device; or disposable reader	

[5] List Price– the price the manufacturer has arrived at for the product, taking into account the cost of goods and other factors (e.g., margin); the list price does not include any volume or other discounts or potential markup for distribution or other costs, including freight, taxes, etc. This cost is assumed a volume production and the prices listed in the TPP are considered for public health preferential pricing in low- and middle-income countries only.

3. Power Requirements	Standard AA/AAA batteries or rechargeable battery with 8-hour operation between charges. Rechargeable battery lifetime > 2 years ~~and less than $50 USD~~	
4. Service, Maintenance and Calibration	Routine preventive maintenance no more than 30 minutes 1x per week (with hands on time <10 minutes). Mean time between failures of at least 36 months or 30,000 tests, whichever occurs first. Self-check alerts operator to reader errors or warnings; and ability to be calibrated remotely, or no calibration needed	
5. Patient Identification Capability	Manual entry of alphanumeric patient identifier keypad or touchscreen compatible with protective gloves	Same, plus bar code, RFID or other reader
6. Result display; result interpretation	Easy pictorial display: positive, negative, or invalid for each target analyte; no instructions for interpretation required	
7. Data acquisition and display	Able to add information (patient ID, operator ID, date, location, etc.); able to store patient results; able to print out results utilizing commoditized paper products (i.e. standard paper specifications and sizes)	
8. Connectivity	Reader has integrated global positioning system (GPS) module	If combined with a reader, internally integrated GPS/ general packet radio service (GPRS) module and conformity with HL7 messaging standards
9. Data export	Full data export over mobile phone network	Full data export over mobile phone network (data transmission can automatically select between GPRS or more advanced networks and global system for mobile communication (GSM), based on available coverage) GPRS should be able to utilize the internet file transfer protocol to transmit data: data transfer should be initiated every 6–12 hours automatically by the reader; data can be exported in a format compatible with HL7 standards, where appropriate; instrument tracks and transmits quality assurance data over time (e.g. identify shifts or trends)
10. Regulatory Requirements	GMP compliant, ISO 13485:2016 certified and authorized for use by a stringent regulatory authority	
11. Cost of Reader	Reader cost included in the list price of the test	

Note: Some common characteristics for POCTs were defined using the WHO NG TPP previously developed, located here: http://www.who.int/reproductivehealth/topics/rtis/pocts/en/