Target product profiles for diagnostic tests for *Taenia solium* taeniasis in humans, and cysticercosis in humans and pigs.

1. Introduction

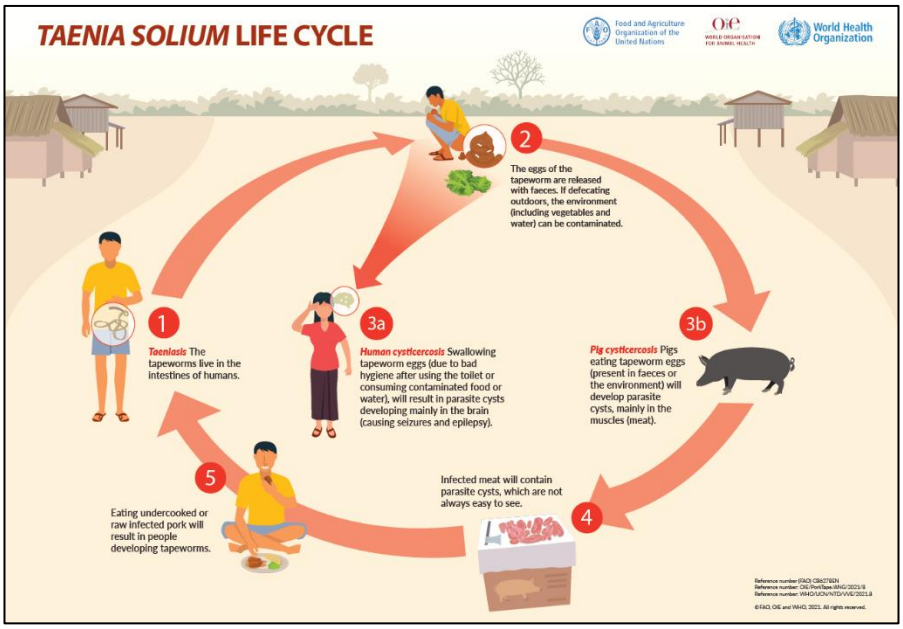
The parasite *Taenia solium* is responsible for causing taeniasis and cysticercosis in humans. Taeniasis refers to the presence of the adult parasite in the intestine, while cysticercosis refers to the presence of the metacestode or larval stage in tissues.

Taeniasis due to *T. solium* is acquired by ingesting raw or undercooked infected pork (Fig. 1), and it is usually asymptomatic or characterized by mild and non-specific intestinal symptoms such as abdominal pain, nausea, diarrhoea, or constipation.

Cysticercosis is acquired by ingesting the tapeworm eggs, usually via the faecal-oral route, or by consuming food or water contaminated by the faeces of persons infected with *T. solium* tapeworms (Fig. 1). The ingested eggs develop into larvae which might encyst in the muscles, skin, or eyes, and often in the central nervous system. Cysticercosis in the central nervous system is known as neurocysticercosis (NCC) and is the most important form of human disease caused by *T. solium*. The clinical signs of cysticercosis and neurocysticercosis will vary depending, amongst other things, on the number of cysts, their location and associated inflammation. NCC is the main cause of acquired epilepsy in low-income countries in which the parasite is present. It has been estimated that NCC causes approximately 30% of epilepsy in areas endemic for *T. solium* but in some communities it can reach up to 70%.

The WHO's 2015 estimates of the global burden of foodborne diseases reported that, in 2010, cysticercosis caused about 28,114 deaths, around 370,710 cases of illness, and approximately 2.8 million disability-adjusted life years (DALYs) lost. These figures are currently being updated and are expected to be higher.

Fig 1: *Taenia solium* life cycle

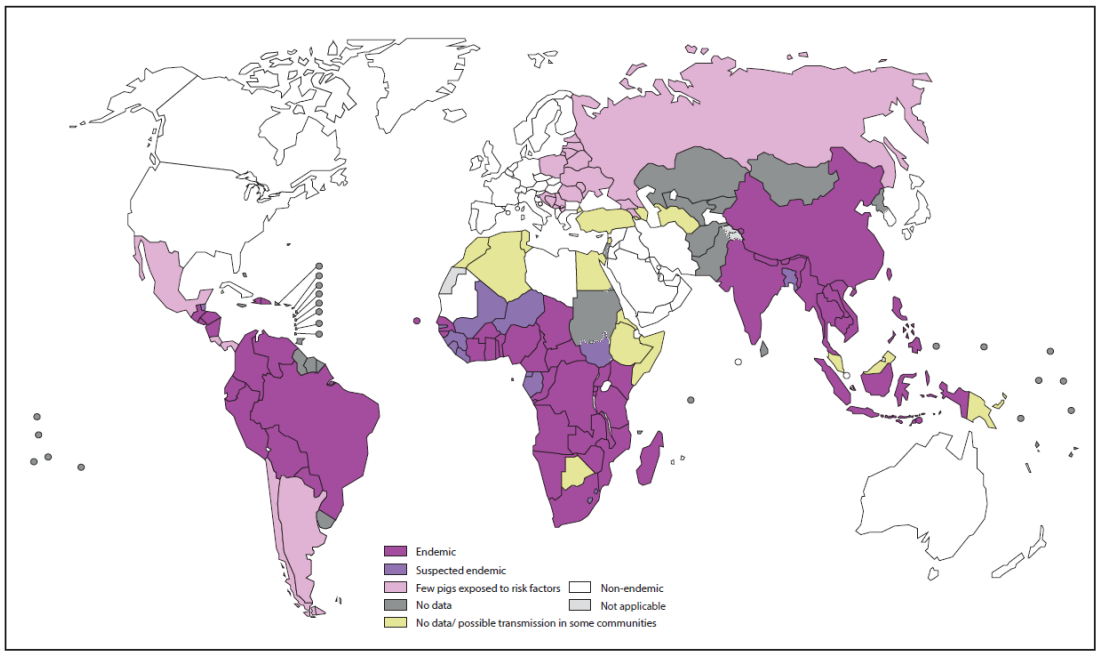


2. Epidemiology

The life cycle of *T. solium* involves humans as definitive host (taeniasis), and pigs as the intermediate host (Fig. 1). *T. solium* taeniasis/cysticercosis is a focal disease, affecting mainly vulnerable communities in which pigs roam free and there is deficient sanitation.

The disease is considered endemic in 51 countries, and suspected endemic in 14 countries. There are 21 countries in which pigs are exposed to the risk factors, and there are 14 countries for which there is no data, or possible transmission in some communities as seen in Fig. 2 (*1*). However, this is a focal disease, and mapping at sub-national level is missing for the large majority of the endemic countries.

Fig 2: Endemicity of *Taenia solium*.



Data Source: World Health Organization
Map Production: Control of Neglected Tropical Diseases (NTD)
World Health Organization

World Health Organization

3. Public health response

The public health response in relation to *T. solium* covers two main areas. One is aimed at a better case management of NCC, and the other one, at the control or interruption of the transmission cycle.

The WHO promotes the appropriate treatment of patients, and has produced guidelines for the management of NCC (*2, 3*). The WHO Expert Consultation held in Vientiane, Lao People's Democratic Republic (*4*), recommended the treatment of human taeniasis and the mass treatment and vaccination of pigs, as the core 'rapid impact' interventions, with community health education and improved sanitation as supporting measures. WHO also supports *T. solium* control programmes, has produced operational guidance and a framework for the monitoring and evaluation of *T. solium* control programmes (*5*), and has a taenicide donation programme.

4. Available diagnostic tools

Public health control programmes: Taeniasis and porcine cysticercosis tests are required to support public health control programmes, as they are the diseases that indicate the active transmission of the parasite. The virtual meeting of experts on the use of existing diagnostic tools for *T. solium* public health programmes (*6*) conducted in 2022, concluded that currently available diagnostic tests for taeniasis and porcine cysticercosis, are not well-suited for mapping and monitoring public health control programmes. Many tests are not adequate in terms of sensitivity and/or species specificity, most tests are not commercially available (or are available only for research use) or are not affordable to programmes in low- and middle-income countries.

- Human taeniasis: Microscopy in faeces, especially Kato–Katz, is used routinely in many countries for the identification of various parasites including *Taenia* spp. However, microscopy techniques are not sensitive and not species-specific. Positive samples should be followed by *Taenia* species parasite identification techniques or molecular methods.
- Porcine cysticercosis: There are no adequate serological tests available. Tongue palpation has a low sensitivity, especially in animals with light infections. Enhanced meat inspection has a low sensitivity (though substantially higher than tongue palpation), especially in animals with light infections.

Case management: The most important disease to diagnose from the case management point of view, is NCC. The internationally recognized criteria for diagnosis of NCC is based on neuroimaging techniques, such as computerized tomography and/or magnetic resonance imaging, ideally supported by serology. These facilities are largely unavailable in highly endemic regions, especially in rural areas of low-income countries, making it difficult to identify and treat patients.

5. Diagnostic Technical Advisory Group for Neglected Tropical Diseases

WHO's Global Neglected Tropical Diseases (NTDs) Programme manages a diverse portfolio of diseases and disease groups, each with its own unique epidemiological and diagnostic challenges. The principal advisory group to WHO on the control, elimination and eradication of NTDs, the Strategic and Technical Advisory Group on NTDs, determined that a single WHO working group would help ensure a unified approach to identifying and prioritising diagnostic needs, and to informing WHO strategies and guidance on the subject (*7*).

In response, the Diagnostic Technical Advisory Group (DTAG) was created. It is an advisory group to the Global NTD Programme. It recommended the establishment of several disease-specific diagnostic sub-groups, including one to advise on One Health surveillance activities, and that TPPs were needed to help test developers focus energies appropriately on tests needed by programmes. A DTAG sub-group of One Health technical experts was formed and first met virtually on 11th December 2024.

6. Purpose of the target product profile

The purpose of these TPPs is to attract developers and companies to invest and lead the development of new diagnostic tools to support case management of NCC cases, and to support *T. solium* control programmes. TPPs are essential to recognize and document gaps, priority areas for diagnostics, use cases, needs statements and requirements for ideal and optimal test characteristics, based on platform-agnostic recommendations.

TPPs for *T. solium* were first developed and published in 2017 (*8*), and those TPPs served as a basis for these new TPPs. The sub-group identified the need for *T. solium* diagnostics in the following areas:

Taeniasis and porcine cysticercosis: Tests that detect *T. solium*-specific analyte(s) to identify areas with ≥ 0.5% prevalence for taeniasis or ≥ 2% prevalence for porcine cysticercosis respectively, for the purposes of 'mapping' and monitoring *T. solium* control programs.

Neurocysticercosis: A Point-of-care test that allows the identification of patients with *T. solium viable* cysts (vesicular and early colloidal cyst stages) in the central nervous system, that would allow to identify:

1- People who might need to be excluded from preventive chemotherapy (PC) with praziquantel (or any drug with systemic effect on the cysts).
2- Individuals with symptoms compatible with NCC in remote areas without access to imaging, for whom the test will provide additional evidence in favour of NCC (in all cases of epilepsy or intracranial hypertension, individuals should be referred to an imaging and specialised treatment service),
3- Individuals requiring post-NCC treatment follow up,

7. Characteristics of a needed diagnostic test for the diagnosis of *T. solium* infection

Three TPPs have been designed. Two for humans and one for pigs. The ones on humans are one for a diagnostic for taeniasis to assist in control programmes by mapping and monitoring (table 1), and other one to support the diagnosis of NCC (table 2). The TPP for porcine cysticercosis is for a diagnostic to assist in control programmes (table 3).

Table 1. TPP for a diagnostic test for *T. solium* taeniasis

Characteristics	Ideal	Minimum
1- Product use summary		
1.1- Use case	Test that detects *T. solium* taeniasis specific analyte(s) to identify areas with ≥ 0.5% prevalence for the purposes of 'mapping' and monitoring *T. solium* control programs.	
1.2- Target population	Humans > 2 years of age in *T. solium* endemic or suspected endemic areas.	
1.3- Lowest infrastructure tier[1]	Tier 2 – Community level	Tier 3 (Health Centre) or above
1.4- Lowest user level	Trained health workers	Skilled laboratory technicians
1.5- Training requirements	½ day	1 day
2- Design		
2.1- Portability	Point-of care. Rapid Diagnostic Test, multiple formats accepted	Any format meeting the performance requirements
2.2- Instrument power/ requirements	Low complexity equipment. Batteries or no power requirement	Laboratory equipment might be required. Some equipment might require mains power, as per manufacturer recommendations (voltage and amperage)

Characteristics	Ideal	Minimum
2.3- Water requirements	Self-contained kit, water not required	Distilled or double deionized water might be required
2.4- Maintenance and calibration	Not required	Readers, pipettes and others to be calibrated as per manufacturer recommendations
2.5- Sample type/ collection	1- Stool (fresh, frozen or fixed with agent compatible with system). OR 2- Capillary whole blood (finger prick) or serum	
2.6- Sample preparation – transfer to device	≤ 2 steps. Samples stable when refrigerated (2-8°C). Samples can be fixed and used for up to 24 months.	≤ 3 steps. Samples stable when refrigerated (2-8°C) for 2 days.
2.7- Sample volume	Stool: 0.1 – 2g Serum or capillary blood: 50 µl	
2.8- Biomarker	Analyte specific for *T. solium* taeniasis active infection	
2.9- Type of analysis	Qualitative	
2.10- Detection	To test negative within 6 days following successful treatment of taeniasis	To test negative within 90 days following successful treatment of taeniasis
2.11- Quality control	1- Exogenous process control indicator (e.g. control line on a rapid diagnostic test (RDT)) 2-Colorimetric or other indicator to identify excessive heat/humidity exposure of the test kit	Exogenous process control indicator (e.g. control line on a rapid diagnostic test (RDT), control well in an ELISA)
2.12- Supplies needed	Minimal supplies to prepare the sample, packaged as a kit	Distilled water, pipettes and tips, timer, laboratory material
2.13- Safety	Does not include material that cannot be disposed of safely in normal health community centres. Minimal or no hazardous materials, as per WHO and country standards	Some moderate hazards permitted (e.g. stopping solutions might contain hazardous substances)
3- Performance		
3.1- Species differentiation	*T. solium* only	
3.2- Analytical Se/ Limit of detection	Positive test would detect the presence of 1 tapeworm (mature or non-gravid).	Positive test would detect the presence of 1 tapeworm within the last 3 months.
3.3- Diagnostic/ Clinical sensitivity[2, 3]	≥ 95%	≥ 95%
3.4- Diagnostic/ Clinical specificity[2, 3]	≥ 99.5%	≥ 99%
3.5- Time to results	< 30 min to develop test result	< 24 hours for any laboratory-based test
3.6- Results stability	≥ 24h	≥ 30 min

Characteristics	Ideal	Minimum
3.7- Throughput	For field-based tests, ≥ 10 tests/h per tester	For laboratory-based tests, ≥ 120 tests/day per tester. For field-based tests, ≥ 7 tests/h per tester
3.8- Target shelf life/ stability	36 months 2-30°C, 2 weeks 50°C	24 months 2-30°C, 2 weeks 40°C (except for reagents that must be kept refrigerated)
3.9- Ease of use	≤ 2 steps; one or no timed steps. No need to transfer small volumes of reagent/sample, no need to measure precise volume of reagents	≤ 3 steps; two or fewer timed steps
3.10- Ease of results interpretation	Easily interpreted by minimally skilled health workers. No possibility for subjective interpretation	Visual readouts with minimal data interpretation
3.11- Operating temperature	10-45°C	20-25°C
3.12- Equivalence of matrices	Results with fixed samples should be equivalent to fresh or frozen samples	Results with fixed samples should be equivalent to fresh or frozen samples, and blood or serum.
3.13- Reproducibility and robustness[2]	Replicate of weak positive, classify the same > 95% of the time	Replicate of weak positive, classify the same > 90% of the time
3.14 – Comparative reference method	Faecal microscopy by Kato Katz or formalin ethyl-acetate concentration followed by molecular test	
4- Product configuration		
4.1- Shipping conditions[4]	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1 (for sterile packaging, if needed); no cold-chain shipping required	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1 (for sterile packaging, if needed); cold-chain shipping (e.g. 0–4 °C) is acceptable for any test components/consumables used in the laboratory
4.2- Storage conditions	Ambient storage conditions, 2–40 °C; no cold storage required	Store between 2-30°C. For laboratory-based tests, cold storage is acceptable for any laboratory-based testing components/ consumables
4.3- Service and support	None required	For laboratory-based tests, support must be available from the manufacturer for any laboratory-based equipment and/or procedure
4.4- Labelling and instructions for use[4]	Compliance required per relevant CE Mark/IVDR requirements (or other SRA, e.g. 21 CFR 820) and WHO prequalification guidance (see WHO TGS-5: *Designing instructions for use for in vitro diagnostic medical devices*); product insert shall be available in relevant local language(s) and English, French, Spanish, and Portuguese. It should include instructions for use of the	Compliance required per relevant CE Mark/IVDR requirements (or other SRA, e.g. 21 CFR 820) and WHO prequalification guidance (see WHO TGS-5: *Designing instructions for use for in vitro diagnostic medical devices*); product insert shall be available in relevant local language(s) and at least English. It should include instructions for use of the test, including diagrams of

Characteristics	Ideal	Minimum
	test, including diagrams of method and results interpretation. Max 2 pages. Must provide accurate material safety data sheet information on components that are potentially toxic	method and results interpretation. Max 4 pages. Must provide accurate material safety data sheet information on components that are potentially toxic
5- Product cost and channels		
5.1- Target pricing per test	≤ 0.5 USD	≤ 2 USD
5.2- Capital cost	No capital costs required	For laboratory-based tests, capital costs may vary
5.3- Product lead times	< 6 weeks	< 8 weeks
5.4- Target launch countries	Countries with endemic areas	
5.5- Product registration	• CE Mark/IVDR (or other stringent regulatory agency) as relevant • Any registration required for export from country of origin • WHO prequalification, if required/applicable • Country-level registration (if required/applicable for target countries)	
5.6- Procurement	Available for procurement by all endemic countries with no restriction	
5.7- Test pack size	≤ 100 tests pack	

Notes:

[1]: See table below for infrastructure tier description.

[2]: Test should be adequately validated, i.e. using field samples from endemic areas with various levels of prevalence, and independently verified.

[3]: Different estimates of sensitivity and specificity can be calculated based on modelling of a two-stage lot quality assurance sampling framework; however, these estimates rely on accepting assumptions about acceptable rates of under- and over-treatment given a specific decision threshold and inter cluster correlations, points for which there is currently no consensus.

[4]: Wherever possible, we have included examples of standards that can be used as guides for the generation of evidence to support claims against the generic characteristics. Please ensure to use the latest versions.

Description of the infrastructure tiers

Infrastructure tier	Description	User
1- Home	Self-testing	Lay person
2- Community	Testing in the community by health workers	Minimally trained health worker (village health workers, paramedics)
3- Clinic / health post (out-patient)	Testing in the clinic by healthcare providers	Clinical staff (health care provider, nurses)
4- Peripheral laboratory	Testing in the peripheral laboratory	Laboratory technician
5- Hospital	Testing of in-patients in hospitals	Hospital staff

Table 2. TPP for the diagnosis of neurocysticercosis (NCC)

Characteristics	Ideal	Minimum
1- Product use summary		
1.1- Use case	A point-of-care test that allows the identification of patients with viable* *T. solium* cyst(s) in the central nervous system (CNS). (*viable: vesicular and early colloidal cyst stages)	
1.2- Target population	1- People who might need to be excluded from PC with praziquantel* 2- Individuals with symptoms compatible with NCC in remote areas without access to imaging, for whom the test will provide additional evidence in favour of NCC (in all cases of epilepsy or intracranial hypertension, individuals should be referred to an imaging and specialised treatment service), 3- Individuals requiring post-NCC treatment follow up. * Or any drug with systemic effect on cysts.	
1.3- Lowest infrastructure tier[1]	Tier 2 – Community level	Tier 3 - Health centre or above
1.4- Lowest user tier	Trained health workers	Skilled laboratory technicians
1.5- Training requirements	½ day	1 day
2- Design		
2.1- Portability	Point-of care. Rapid Diagnostic Test, multiple formats accepted	
2.2- Instrument power/ requirements	Low complexity equipment. Batteries or no power requirement	Timing device required
2.3- Water requirements	Self-contained kit, water not required	
2.4- Maintenance and calibration	Not required	
2.5- Sample type/ collection	Capillary whole blood (finger prick), serum, saliva or urine.	Capillary whole blood (finger stick) or serum
2.6- Sample preparation – transfer to device	≤ 2 steps. Samples stable when refrigerated (2-8°C).	
2.7- Sample volume	Blood/serum: < 10 µl Saliva: < 1 mL Urine: < 1 mL	Blood/serum: < 50 µl Saliva: < 1 mL Urine: < 10 mL
2.8- Biomarker	Specific biomarker to detect *T. solium* cysts requiring anthelmintic treatment	
2.9- Type of analysis	Semi-quantitative or quantitative	Qualitative
2.10- Detection	Does not detect transient positives. Does not detect viable cysts outside the CNS.	Does not detect transient positives.
2.11- Quality control	1- Exogenous process control indicator (e.g. control line on a rapid diagnostic test (RDT), control well in an ELISA).	

Characteristics	Ideal	Minimum
	2-Colorimetric or other indicator to identify excessive heat/humidity exposure of the test kit	
2.12- Supplies needed	Minimal supplies to prepare the sample, packaged as a kit	
2.13- Safety	Does not include material that cannot be disposed of safely in normal health community centres. Minimal or no hazardous materials, per WHO and country standards	
3- Performance		
3.1- Species differentiation	*T. solium* only	
3.2- Analytical Se/ Limit of detection	Patients with a single intracranial viable cyst, including intra or extra parenchymal cysts	Patients with 1 or more viable parenchymal cysts, OR a single ventricular or subarachnoid cysticercus.
3.3- Diagnostic/ Clinical sensitivity	≥ 99%	80% - 1 cyst 95% - 2 or more cysts
3.4- Diagnostic/ Clinical specificity[2]	≥ 95%	≥ 90%
3.5- Time to results	< 30 min to develop test result	< 2 hours to develop test result
3.6- Results stability	≥ 24 hrs	≥ 30 mins
3.7- Throughput	For field-based tests, ≥ 10 tests/h per tester	For field-based tests, ≥ 7 tests/h per tester
3.8- Target shelf life/ stability	36 months 2-30°C, 2 weeks 50°C	24 months 2-30°C, 2 weeks 40°C
3.9- Ease of use	≤ 2 steps. One or no timed steps. No need to transfer small volumes of reagent/sample, no need to measure precise volume of reagent or weight samples	≤ 3 steps; two or fewer timed steps
3.10- Ease of results interpretation	Easily interpreted by minimally skilled health workers. No possibility for subjective interpretation	Visual readouts with minimal data interpretation
3.11- Operating temperature	10-45°C	20-25°C
3.12- Equivalence of matrices	Results with serum, saliva or urine should be equivalent	
3.13- Reproducibility and robustness[3]	Replicate of weak positive, classify the same > 95% of the time	Replicate of weak positive, classify the same > 90% of the time
3.14 Comparative reference method	Imaging as per WHO guidelines on management of *Taenia solium* neurocysticercosis (*2*)	
4- Product configuration		
4.1- Shipping conditions[3]	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1 (for sterile packaging, if needed); no cold-chain shipping required	

Characteristics	Ideal	Minimum
4.2- Storage conditions	Ambient storage conditions, 2–40 °C; no cold storage required	Store between 2-30°C; no cold storage required
4.3- Service and support	None required	
4.4- Labelling and instructions for use[3]	Compliance required per relevant CE Mark/IVDR requirements (or other SRA, e.g. 21 CFR 820) and WHO prequalification guidance (see WHO TGS-5: *Designing instructions for use for in vitro diagnostic medical devices*); product insert shall be available in relevant local language(s) and English, French, Spanish, and Portuguese. It should include instructions for use of the test, including diagrams of method and results interpretation. Max 2 pages. Must provide accurate material safety data sheet information on components that are potentially toxic	Compliance required per relevant CE Mark/IVDR requirements (or other SRA, e.g. 21 CFR 820) and WHO prequalification guidance (see WHO TGS-5: *Designing instructions for use for in vitro diagnostic medical devices*); product insert shall be available in relevant local language(s) and at least English. It should include instructions for use of the test, including diagrams of method and results interpretation. Max 4 pages. Must provide accurate material safety data sheet information on components that are potentially toxic
5- Product cost and channels		
5.1- Target pricing per test	≤ 2 USD / test	≤ 3 USD / test
5.2- Capital cost	No capital costs required	
5.3- Product lead times	< 6 weeks	< 8 weeks
5.4- Target launch countries	Countries with endemic areas	
5.5- Product registration	• CE Mark/IVDR (or other stringent regulatory agency) as relevant • Any registration required for export from country of origin • WHO prequalification, if required/applicable • Country-level registration (if required/applicable for target countries)	
5.6- Procurement	Available for procurement by all endemic countries with no restriction	
5.7- Test pack size	≤ 10 tests/pack	≤ 25 tests pack

Notes:

[1]: See Note 1 for the Taeniasis TPP.

[2]: Test should be adequately validated, i.e. using samples from patients with different NCC presentations, and independently verified.

[3]: Wherever possible, we have included examples of standards that can be used as guides for the generation of evidence to support claims against the generic characteristics. Please ensure to use the latest versions.

Table 3. TPP for the diagnosis of porcine cysticercosis

Characteristics	Ideal	Minimum
1- Product use summary		
1.1- Use case	Test that detects *T. solium* cysticercosis specific analyte(s) to identify areas with ≥ 2% disease prevalence* for the purpose of 'mapping' and monitoring *T. solium* control programs. *: in the pig population (not at farm level)	
1.2- Target population	Any pig population in which *T. solium* is suspected.	
1.3- Lowest infrastructure tier	Basic infrastructure including local animal health care facilities and sub-national laboratories	Diagnostic facilities including research laboratories
1.4- Lowest user level	Animal health workers with appropriate training	Skilled laboratory technicians
1.5- Training requirements	½ day	1 day
2- Design		
2.1- Portability	Point-of care. Rapid Diagnostic Test, multiple formats accepted	Any format meeting the performance requirements
2.2- Instrument power/ requirements	Low complexity equipment. Batteries or no power requirement	Laboratory equipment might be required. Some equipment such might require mains power, as per manufacturer recommendations (voltage and amperage)
2.3- Water requirements	Self-contained kit, water not required	Distilled or double deionized water might be required
2.4- Maintenance and calibration	Not required	Readers, pipettes and others to be calibrated as per manufacturer recommendations
2.5- Sample type/ collection	Blood (spots, ear pricks & swabs), oral fluids	Serum, plasma or blood
2.6- Sample preparation – transfer to device	≤ 2 steps. Samples stable when refrigerated (2-8°C)	≤ 3 steps. Samples stable when refrigerated (2-8°C)
2.7- Sample volume	≤ 50 μL	≤ 500μL
2.8- Biomarker	Specific biomarker for the presence of viable *T. solium*	
2.9- Type of analysis	Qualitative	
2.10- Detection	To test positive only in the presence of viable cysts. To test negative 4 weeks following effective treatment. Not to test positive after vaccination.	To test positive only in the presence of viable cysts[1]. To test negative 10 weeks following effective treatment of muscle cysts. Not to test positive after vaccination.
2.11- Quality control	1- Exogenous process control indicator (e.g. control line on a rapid diagnostic test (RDT), control well in an ELISA). 2-Colorimetric or other indicator to identify excessive heat/humidity exposure of the test kit	Exogenous process control indicator (e.g. control line on a rapid diagnostic test (RDT), control well in an ELISA)

Characteristics	Ideal	Minimum
2.12- Supplies needed	Minimal supplies to prepare the sample, packaged as a kit	Distilled water, pipettes and tips, timer, laboratory material
2.13- Safety	Does not include material that cannot be disposed of safely in normal health community centres. Minimal or no hazardous materials	Some moderate hazards permitted (e.g. stopping solutions might contain hazardous substances)
3- Performance		
3.1- Species differentiation	*Taenia solium* cysticercosis only	
3.2- Analytical Se/ Limit of detection	Positive test would detect the presence of ≥1 viable cyst	
3.3- Diagnostic/ Clinical sensitivity[2, 3]	< 10 cysts 90%, ≥ 10 cysts 99%	< 50 cysts 70%, ≥50 cysts 90%
3.4- Diagnostic/ Clinical specificity[2, 3]	≥ 98%. Validation in endemic settings. No cross reactions with exposure to, or infection with, other parasite species or show transient positive responses in absence of mature viable cysts	≥ 95%. Validation in endemic settings. No cross reactions with exposure to, or infection with, other parasite species or show transient positive responses in absence of mature viable cysts
3.5- Time to results	< 30 min to develop test result	< 24 hours for any laboratory-based test
3.6- Results stability	≥ 24 hrs	≥ 30 mins
3.7- Throughput	For field-based tests, ≥ 10 tests/h per tester	For laboratory-based tests, ≥ 120 tests/day per tester. For field-based tests, ≥ 7 tests/h per tester
3.8- Target shelf life/ stability	36 months 2-40°C	24 months 2-30°C, 2 weeks 40°C (except for reagents that must be kept refrigerated)
3.9- Ease of use	≤ 2 steps. One or no timed steps. No need to transfer small volumes of reagent/sample, no need to measure precise volume of reagent or weight samples	≤ 3 steps; two or fewer timed steps
3.10- Ease of results interpretation	Easily interpreted by minimally skilled health workers. No possibility for subjective interpretation	Visual readouts with minimal data interpretation
3.11- Operating temperature	10-45°C	20-25°C
3.12- Equivalence of matrices	Blood, serum, oral fluids	Serum, plasma or blood
3.13- Reproducibility and robustness	Replicate of weak positive, classify the same > 95% of the time	Replicate of weak positive, classify the same > 90% of the time
3.14	Necropsy, full carcass and brain dissection	

Characteristics	Ideal	Minimum
Comparative reference method		
4- Product configuration		
4.1- Shipping conditions[4]	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1 (for sterile packaging, if needed); no cold-chain shipping required	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1 (for sterile packaging, if needed); cold-chain shipping (e.g. 0–4 °C) is acceptable for any test components/consumables used in the laboratory
4.2- Storage conditions	Ambient storage conditions, 2–40 °C; no cold storage required	Store between 2-30°C. For laboratory-based tests, cold storage is acceptable for any laboratory-based testing components/ consumables
4.3- Service and support	None required	For laboratory-based tests, support must be available from the manufacturer for any laboratory-based equipment and/or procedures
4.4- Labelling and instructions for use	Compliance as per WOAH Terrestrial Manual (Chapter 1.1.3). Product insert shall be available in relevant official language(s) as per local legislation, and at least in English, French, Spanish, and Portuguese, and shall include instructions for use for the test, including diagrams of method and results interpretation. Maximum 2 pages. Must provide accurate material safety data sheet information on components that are potentially toxic	Compliance as per WOAH Terrestrial Manual (Chapter 1.1.3). Product insert shall be available in relevant official language(s) as per local legislation, and at least in English, and shall include instructions for use for the test, including diagrams of method and results interpretation. Maximum 4 pages. Must provide accurate material safety data sheet information on components that are potentially toxic
5- Product cost and channels		
5.1- Target pricing per test	≤ 0.5 USD / test	≤ 2 USD / test
5.2- Capital cost	No capital costs required	For laboratory-based tests, capital costs may vary
5.3- Product lead times	< 6 weeks	< 8 weeks
5.4- Target launch countries	Countries with endemic areas	
5.5- Product registration	• Any registration required for export from country of origin • Country-level registration (if required/applicable for target countries)	
5.6- Procurement	Available for procurement by all endemic countries with no restriction	
5.7- Test pack size	≤ 50 tests/pack	≤ 100 tests pack

Notes:

[1]: Consideration was given to the possibility of including non-viable cysts, but because the test should be adequate for monitoring control programmes using oxfendazole (or other suitable drug that might become available), the TPP was limited to viable cysts as to maintain the broad use case described.

[2]: Test should be adequately validated, i.e. using field samples from endemic areas with various levels of prevalence, and independently verified.

[3]: Different estimates of sensitivity and specificity can be calculated based on modelling of a two-stage lot quality assurance sampling framework; however, these estimates rely on accepting assumptions about acceptable rates of under- and over-treatment given a specific decision threshold and inter cluster correlations, points for which there is currently no consensus.

[4]: Wherever possible, we have included examples of standards that can be used as guides for the generation of evidence to support claims against the generic characteristics. Please ensure to use the latest versions.

8. References

1. Donadeu M, Bote K, Gasimov E, Kim SH, Lin Z, Lucianez A, et al. WHO *Taenia solium* endemicity map – 2022 update. Weekly epidemiological record. 2022;97(17):169-72.
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