Target product profiles for the diagnostic of *Echinococcus granulosus* in humans, dogs, and sheep.

1. Introduction

The parasite *Echinococcus granulosus sensu lato* is responsible for causing cystic echinococcosis (CE) in humans, a neglected parasitic zoonosis. It leads to the development of one or more CE cysts located most often in the liver and lungs, and less frequently in the bones, kidneys, spleen, muscles, heart, central nervous system and virtually any other body location. The impact of the infection varies with the number, location and size of the cysts and, when symptomatic, manifests commonly with pain and compromised organ function, worsening as the cysts enlarge. The asymptomatic incubation period can last many months, years or even be lifelong, until the CE cysts grow to an extent that triggers symptoms or signs or when the cyst's integrity is damaged. Untreated cysts might also pose a risk of rupture, which can result in severe complications such as anaphylactic shock, disseminated infection or mortality.

The WHO estimates of the global burden of foodborne diseases 2015 (*1*), showed for 2010 a median of 2,225 deaths (95% CI 749–19,627), a median illness of 188,079 cases (95% CI 156,848–1,770,40), and a median of 183,573 (95% CI 88,082–1,590,846) disability-adjusted life-years (DALYs) . These estimates are being updated at the time of writing this report, and will likely be higher.

2. Epidemiology

E. granulosus s.l. is genetically complex, involving numerous species or genotypes, not all of which cause infection in humans. Two species of *E. granulosus s.l.* are responsible for almost all recorded CE human infections (*2*): *E. granulosus sensu stricto* (*s.s.;* G1, G3) and *E. canadensis* (G6, G7).

The life cycle of *E. granulosus s.l.* involves two animal hosts: the definitive and intermediate hosts. The definitive hosts are typically canids, mainly dogs, and the adult tapeworm resides in their small intestine, producing eggs that are excreted in faeces. These eggs contaminate the environment (soil, grass, vegetables, water) and can be ingested by intermediate hosts. The intermediate hosts are typically livestock, mainly sheep, although other animals such as cattle, goats, camels, yaks, pigs and wild herbivores can also be infected. In the intermediate hosts, the parasite develops into the metacestode, named echinococcal cyst, in body organs. Transmission to definitive hosts occurs when they ingest infected intermediate host tissues containing fertile cysts, resulting in the development of adult tapeworms (*3*).

Humans become infected by accidentally ingesting parasite eggs from fomites (e.g., hands, food, water) contaminated with eggs shed with the faeces of a definitive host. CE is a focal disease, affecting mainly pastoral and rural communities. It is a significant public health problem in large pastoral areas in South America, North Africa, Eastern and Mediterranean Europe, the Middle East, Central Asia, the Russian Federation and China *(4)*.

3. Public health response

Cystic echinococcosis control is based on One Health interventions, aimed at breaking the transmission cycle between definitive and intermediate hosts. The interventions include regular deworming of dogs with praziquantel, management of non-owned dogs, vaccination of

intermediate hosts with the EG95 vaccine, safe disposal of infected offal, and culling of old sheep.

Treatment of infected humans has no impact on the transmission of the infection. Prevention of infection in humans is based on health promotion and includes awareness and education of the at-risk communities, and unspecific food and hands hygiene practices.

CE is expensive and complex to treat. The clinical management approach is primarily guided by cysts' characteristics (stage, number, size, organs affected, localization within organs) and the signs and symptoms presented by the patient (complicated/uncomplicated CE), taking also into account patient factors such as age and comorbidities, and access to health infrastructures *(5)*. Clinical management strategies include prolonged drug treatment, percutaneous interventions, surgery (both always associated with drug treatment), or observation without active treatment (watch-and-wait). While CE may result in severe complications which are disabling and even life-threatening if left untreated, not all CE patients require treatment, and not all require invasive treatment. Inappropriate clinical management may lead to iatrogenic complications and reduced quality of life.

The WHO supports CE control programmes and promotes the appropriate treatment of patients; has recently released the WHO guidelines for the treatment of patients with CE (*5*), and has an albendazole donation programme.

4. Available diagnostic tools

Human CE: The current diagnosis of CE is based on imaging techniques, primarily ultrasound or magnetic resonance imaging, while computed tomography is less reliable (*5, 6*). While artificial intelligence-aided imaging interpretation tools have been explored to support the differential diagnosis of CE versus other focal lesions, none has currently adequate accuracy for practical implementation to support the differential diagnosis of CE-looking lesions. Imaging diagnosis is complemented by laboratory-based techniques, often including serology but also analysis of cyst's material obtained invasively, when imaging is not conclusive. No antigen detection tests are commercially available. Antibody detecting serological tests complement imaging findings, yet their limitations warrant careful consideration. Cyst staging, localization, and loss of cyst's integrity are known to be associated with the performance of serological assays, so these characteristics need to be described when evaluating an assays' sensitivity; this is lacking for many existing tests. In addition, specificity should be evaluated on clinically relevant groups, which is also seldomly performed.

Dog echinococcosis: Microscopy for the detection of parasite eggs in dog's faeces has limited value because *E. granulosus* eggs are indistinguishable from eggs of other taeniids. Regarding laboratory tests, other than in China, there are no commercially available diagnostic tests for canine echinococcosis. Published methods include copro-ELISA, copro-PCR and LAMP (*7*). Copro-ELISA tests utilize polyclonal antibodies and have limitations in relation to specificity, which is the most important characteristic for a test to be deployed at population level. In addition, difficulties have been experienced with reproducibility with both copro-PCR and copro-ELISA tests in endemic settings (*8*). There is an urgent need for improved diagnostic methods and commercial production of these tests.

Hydatidosis in sheep/goats: Carcass inspection after slaughter continues to be the main diagnostic method used for animal intermediate hosts. Ultrasound has been used in sheep, particularly for research purposes. There are no serological tests available.

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 (*9*).

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. The specific meetings focused on CE started on 24th June 2025, with the contribution of additional matter experts.

6. Purpose of the target product profile

The purpose of this TPPs is to attract developers and companies to invest and lead the development of new diagnostic tools to support case management of CE cases, and to support CE 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.

The sub-group identified the need for CE diagnostics in the following areas:

Humans: To support case management after imaging; specifically, after a lesion compatible with CE morphology is observed on imaging, to refer potential CE cases to expert consultation and clinical management. While TPPs were developed specifically for laboratory-based assays, performance characteristics could be used to guide also the development of artificial intelligence-aided imaging interpretation tools.

Dogs, sheep/goats: Tests that could assist with:
1. monitoring and reporting on the effectiveness of *E. granulosus* control programmes.
2. 'mapping' CE transmission (identify active transmission)

The advantage of testing dogs is that there are fewer of them, the infection could be detected earlier, and samples could be also collected from faeces in the environment. The testing of sheep/goats could be useful for young animals, when animals are not slaughtered in official, regulated slaughterhouses and it might provide opportunities for integration with livestock routine testing (if applicable in the local context).

7. Characteristics of a needed diagnostic test for the diagnostic of cystic echinococcosis in humans

Three TPPs have been designed. One to address the needs for supporting management of potential CE cases in humans (table 1), and two to assist in control programmes: one for dogs (table 2), and one for sheep/goats (table 3).

Table 1. TPP for case management of CE

Characteristics	Ideal	Minimum
1- Product use summary		
1.1- Use case	Test for case management of CE cysts: after imaging, for referring potential cases to expert consultation and clinical management[1]	Test for case management of CE **liver** cysts: after imaging, for referring potential cases to expert consultation and clinical management
1.2- Target population	Humans **with focal lesions in any organ**, the echinococcal aetiology of which cannot be confirmed or excluded on the basis of recognition of pathognomonic features on imaging	Humans with focal **liver** lesions the echinococcal aetiology of which cannot be confirmed or excluded on the basis of recognition of pathognomonic features on imaging
1.3- Lowest infrastructure level[2]	Level 2 - Clinic/health post (out-patient) with access to basic imaging (e.g. ultrasound, chest X ray)	Level 4 or above - Peripheral laboratory/hospital
1.4- Lowest user level	Trained health workers	Laboratory technicians/hospital staff
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)
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	Capillary whole blood (finger prick), saliva, urine, or breath	Serum or plasma, possibly also obtained from whole blood collected on dried blood spots
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	Urine: < 1 mL Blood/serum/plasma: < 10 µL Saliva: < 1 mL	Urine: < 10 mL Blood/serum: < 50 µL Saliva: < 1 mL
2.8- Biomarker	*E. granulosus*-specific biomarker to identify the *E. granulosus s.l.* etiology of focal lesions identified by imaging	
2.9- Type of analysis	The test should not be negative in the presence of an inactive CE cysts but different cut-off thresholds for active/inactive cysts should be given	Qualitative to detect any CE cyst stage
2.10- Detection	Does not detect transient positives	Might need to be repeated to confirm that the result is not a transient positive

Characteristics	Ideal	Minimum
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	*E. granulosus s.l.* only	*E. granulosus s.l.* only
3.2- Analytical Se/ Limit of detection	Patients with a single CE cyst **in any stage in any organ/tissue**	Patients with a single CE cyst **in any stage in the liver**
3.3- Diagnostic/ Clinical sensitivity[3]	≥95%	≥95%
3.4- Diagnostic/ Clinical specificity[3]	≥98%	≥95%
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
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	5-45°C	20-25°C
3.12- Equivalence of matrices	Equivalence whole blood, serum, plasma, saliva, urine; equivalence of serum/plasma obtained from fresh whole blood or from blood on dried blood spots	Equivalence serum and plasma

Characteristics	Ideal	Minimum
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 – Comparative reference method	Reference standard imaging interpreted by an expert on CE imaging	Reference standard imaging interpreted by an expert on CE imaging
4- Product configuration		
4.1- Shipping conditions	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1:2019 (for sterile packaging, if needed); no cold-chain shipping required	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1:2019 (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	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, Chinese, Russian and Arab. 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	≤5 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 and countries with relevant immigration of patients from endemic areas	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	

Characteristics	Ideal	Minimum
	• 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	≤ 100 tests pack

Notes:

[1]: Ideal refers to CE cysts in any location; minimum refers to CE cysts in the liver.

[2]: See table below for level description.

[3]: Sensitivity and specificity thresholds were calculated based on the estimate of the relative proportion of aetiologies causing focal lesions when the real prevalence of CE in the population is 5%, to reach a post-test probability of the lesion being CE of at least 90% (if test positive) and a negative probability of the lesion being CE of less than 2% (if test is negative). NB for focal lesions in extrahepatic abdominal organs, due to the low pre-test probability of CE (5%), positive post-test probability will only reach 70%.

Description of the infrastructure levels

Infrastructure level	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 (doctors, 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 canine echinococcosis

Characteristics	Ideal	Minimum
1- Product use summary		
1.1- Use case	Test that detects *Echinococcus granulosus* specific analyte(s) to identify areas with ≥ 1% disease prevalence* for the purpose of: 1. monitoring and reporting on the effectiveness of *E. granulosus* control programmes. 2. 'mapping' CE transmission (identify active transmission) *: in the dog population (not at farm level)	
1.2- Target population	Any dog living in areas in which transmission of *E. granulosus sensu lato* is suspected (in humans or animals)	
1.3- Lowest infrastructure level	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

Characteristics	Ideal	Minimum
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)
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	Faeces (fresh, frozen or fixed). Samples could be collected from the ground	Faeces (fresh, frozen or fixed), rectal swabs, capillary whole blood or serum. Faecal samples could be collected from the ground
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).
2.7- Sample volume	≤ 0.5 g faeces	≤ 2 g faeces; ≤50µL blood/serum
2.8- Biomarker	Specific biomarker for the presence and differentiation of viable *E. granulosus sensu stricto* and *E. granulosus sensu lato*	Specific biomarker for the presence of *E. granulosus sensu lato*
2.9- Type of analysis	Qualitative	Qualitative
2.10- Detection	To test negative within 6 days following successful anthelmintic treatment	To test negative within 90 days following successful anthelmintic treatment[1]
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).
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). Safe disposal of stool samples
3- Performance		
3.1- Species differentiation	*E. granulosus sensu stricto* and *E. granulosus sensu lato*	*E. granulosus sensu lato*
3.2- Analytical Se/ Limit of detection	Positive test would detect the presence of ≥1 adult worm	Positive test would detect the presence of ≥50 adult worms[2]
3.3- Diagnostic/ Clinical sensitivity	≥99%	≥80%
3.4- Diagnostic/ Clinical specificity	≥99%	≥95%

Characteristics	Ideal	Minimum
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	Easyly interpreted by minimally skilled health workers. No possibility for subjective interpretation	Visual readouts with minimal data interpretation
3.11- Operating temperature	5-45°C	20-25°C
3.12- Equivalence of matrices	Results with fixed faeces should be equivalent to fresh or frozen samples	Faeces, rectal swabs, capillary whole blood or serum
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 Comparative reference method	Necropsy, examination of small intestine or arecoline purge[3]	
4- Product configuration		
4.1- Shipping conditions	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1:2019 (for sterile packaging, if needed); no cold-chain shipping required	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1:2019 (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 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, Chinese, Russian, and	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

Characteristics	Ideal	Minimum
	Arabic, 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	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	≤3 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	≤10 tests/pack	≤ 100 tests pack

Notes:

[1]: 90 days because the test can be conducted using serum.

[2]: 50 worms is the limit of the best the copro-Antigen assays described to date.

[3]: Only for validation of the tests. Roadkill could be used for validation. Use of arecoline might not be allowed in some countries. A standardised validation procedure for the examination of the small intestine should be used, as the one described in the Terrestrial Manual of the World Organisation for Animal Health (chapter 3.1.6) (*11*)

Table 3. TPP for echinococcosis in sheep and goats

Characteristics	Ideal	Minimum
1- Product use summary		
1.1- Use case	Test that detects *Echinococcus granulosus* - specific analyte(s) to identify areas with ≥ 5% disease prevalence* for the purpose of: 1- monitoring and reporting on the effectiveness of *E. granulosus* control programmes. 2- 'mapping' CE transmission *: in the sheep and goat population using abattoir data as reference	
1.2- Target population	Sheep and goats ≥1 year of age living in areas in which transmission of *E. granulosus sensu lato* is suspected (in humans or animals)	
1.3- Lowest infrastructure level	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

Characteristics	Ideal	Minimum
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	Capillary whole blood or serum	
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	≤ 150μL
2.8- Biomarker	Specific biomarker for the presence and differentiation of viable *E. granulosus sensu stricto* and *E. granulosus sensu lato*	Specific biomarker for the presence of *E. granulosus sensu lato*
2.9- Type of analysis	Qualitative	Qualitative
2.10- Detection	Does not detect transient positives	Might need to be repeated to confirm that the result is not a transient positive
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)
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	*E. granulosus sensu stricto* and *E. granulosus sensu lato*	*E. granulosus sensu lato*
3.2- Analytical Se/ Limit of detection	Positive test would detect the presence of ≥1 viable cyst	Positive test would detect the presence of ≥1 cyst
3.3- Diagnostic/ Clinical sensitivity	≥99%	≥80%

Characteristics	Ideal	Minimum
3.4- Diagnostic/ Clinical specificity[1]	≥99%	>95%
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	5-45°C	20-25°C
3.12- Equivalence of matrices	Blood, serum	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 Comparative reference method	Necropsy, slicing liver and lungs	
4- Product configuration		
4.1- Shipping conditions	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1:2019 (for sterile packaging, if needed); no cold-chain shipping required	Conformance to applicable requirements of ASTM D4169–05 (for shipping) and ISO 11607-1:2019 (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

Characteristics	Ideal	Minimum
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 Chinese, Russian, and Arabic, 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]: Proven to be able to differentiate infected from uninfected sheep within the same flock

8. References

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