

User guide for the submission and acceptance of samples for *Cryptosporidium* slide genotyping

Contents

1	DEFINITION AND SCOPE	2
2	PURPOSE AND OUTLINE OF TESTING.....	2
3	RESPONSIBILITIES	2
4	PROCEDURE.....	3
4.1	Sample submission	3
4.2	Sample receipt and processing	5
4.2.1	Urgent samples.....	5
4.2.2	Non-urgent (operational monitoring) samples.....	5
5	RESULT REPORTING	5
	APPENDIX 1.....	7
	APPENDIX 2: PUBLIC HEALTH WALES' FOOD, WATER AND ENVIRONMENTAL SERVICE (FWES)	9

1 Definition and Scope

Cryptosporidium genotyping is a specialist test provided by the national *Cryptosporidium* Reference Unit (CRU) in Swansea. It is not available in most water-testing, clinical diagnostic or public health Food, Water and Environment laboratories. The results can be used as part of risk assessment processes. This document defines the responsibilities of each party (purchaser and CRU) with regard to sample submission, acceptance for testing and reporting. Further information is available in Appendix 1: the submission form, and on our website <https://phw.nhs.wales/services-and-teams/cryptosporidium-reference-unit-water-and-environmental-services/> or directly from the *Cryptosporidium* Reference Unit. Please also see the Public Health Wales' FWES terms and conditions (Appendix 2).

The purchaser is the laboratory sending the slides for genotyping.

2 Purpose and outline of testing

Water companies find it useful to include *Cryptosporidium* slide genotyping to contribute to risk assessments for their treatment works (including the water source and catchment), operational monitoring, and investigation of events (root cause analysis). Slide genotyping may also be requested by outbreak control teams and the regulator during the investigation of outbreaks.

Any of the above instances involve the exchange of appropriate paperwork between the purchaser and CRU and the safe exchange of samples or goods which can easily be traced if necessary. In order to guarantee that everything reaches its destination and that nothing is lost in transit this procedure must be adhered to by both parties.

The tests used in this procedure are based on polymerase chain reaction (PCR) and there is a positive relationship between the number of *Cryptosporidium* oocysts seen on slides and the success of slide genotyping (typeability). Typeability may also be reduced due to unpredictable factors often present in water samples which may prevent reporting of useful results. Slides from water that have been subjected to UV treatment are not suitable for genotyping. Users should be aware of these limitations when considering whether to send slides.

This is a destructive test and the slides will not be available after testing.

3 Responsibilities

It is the responsibility of both the customer and the CRU to ensure that work is properly sent and received from either party. At CRU samples are receipted, and booked in to the auditable LIMS.

4 Procedure

4.1 Sample submission

Two services are offered - 1) a monthly service, for operational or event management, or 2) urgent investigation of a public health emergency.

If a water company wishes to send slides for genotyping, irrespective of the number of oocysts on the slide, that are associated with an ongoing event, or potential public health emergency (e.g. boil advice has been issued or is likely to be issued), then the water company should contact the CRU before the slides are sent, to discuss the on-going situation, ensure likely outcomes are made clear, and that the time required to obtain a result is agreed.

Laboratories are also advised to consult with the CRU before submitting slides with < 5 oocysts, as genotyping will not be fruitful for all such slides and should be as part of a structured investigation. For example, one-off detections of single oocysts may not warrant genotyping, whereas genotyping a series of *Cryptosporidium*-positive slides from a source/supply may help inform catchment and risk management decisions. To facilitate this, slides could be kept under refrigerated conditions at the test laboratory, and considered for genotyping if a situation emerges that warrants it. The CRU can provide advice on investigations.

Initial enquiries must be made by telephone: 01792 285341 or email to swansea.crypto@wales.nhs.uk.

All samples submitted to the CRU must be accompanied by a completed Submission Form "Form 3: Genotyping from water testing slides", available from our website (<https://phw.nhs.wales/services-and-teams/cryptosporidium-reference-unit-water-and-environmental-services/cryptosporidium-swimming-pool-documents/form-3-slide-genotyping-request-form/>)

This form must be e-mailed (swansea.crypto@wales.nhs.uk) to the CRU prior to sending samples, and a hard copy included in the package with the samples.

The samples may be sent by either Royal Mail Special Delivery (preferred method), international equivalent, or by courier from the purchaser to the CRU, accompanied by the relevant paperwork.

Fixed microscopy slides are non-infectious and can be sent in suitable packaging, with slides contained within a suitable slide holder.

Specific guidance for submitting slides and associated paperwork:

In the past, the CRU has received slides from contract laboratories with no information of the source or supply. This has made it difficult to interpret results and provide advice especially if a public health incident should arise. An agreement can be set up between receiving labs and commissioning water undertakers to enable this information to be shared. Note that the CRU accepts its responsibilities on duty of care and client confidentiality. Please ensure on the request form that the *Client Water Company* is named, and the *Sample Source Information* column is completed, including the name of the Water Treatment Works where applicable. Slides submitted without these details may be rejected.

Slides prepared with reagents incorporating chemicals that may interfere with PCR will not be accepted for genotyping. Examples include formalin which may be in mounting media or other buffers. Laboratories are advised to check the composition of reagents with their reagent supplier and state the product code on the sample request form. Slides prepared with such reagents will be rejected if sent for genotyping, as may those for which this information is not provided.

Slides prepared from samples that have been exposed to ultraviolet (UV) irradiation, for example as part of the water treatment process, are not suitable for genotyping will not usually be accepted. UV treatment damages the DNA resulting in the inhibition of PCR amplification.

Laboratories are advised to use single-well slides for microscopy to avoid the risk of cross-contamination. Multi-well slides used for anything other than split samples will be rejected if sent for genotyping.

The requirement for sending a process negative slide has been removed as the process of slide genotyping is adequately controlled by the inclusion of negative control material during processing and testing.

Samples from the same incident/outbreak/investigation may be sent in the same package but samples from different investigations must be separated within the package and with separate paperwork.

If requested, the CRU will acknowledge receipt of each package by completing and email back a receipt *pro-forma* if provided by the sender, on the day of arrival.

Unfixed material e.g. IMS pellets, are potentially infectious and must sent as "Diagnostic specimens" and packaged under current IATA 650 transport regulations with the UN3373 warning notice. Submission of this type of sample must be discussed with the CRU ahead of sending.

4.2 Sample receipt and processing

4.2.1 Urgent samples

Samples received before 12 noon will be processed that day; samples received after this time cannot be guaranteed to be processed on the same day. The normal turnaround time is up to 4 working days, but may be extended to 5 working days if the samples are received after 12 noon.

Please note that under normal circumstances, the CRU does not offer testing at weekends and samples may not be accepted into the laboratory outside normal office hours. Separate arrangements for such circumstances need to be made in advance.

4.2.2 Non-urgent (operational monitoring) samples

This test is offered monthly, at the beginning of each month; slides received by the end of the previous month will be included.

The testing process is time-consuming and limited by maximum batch sizes for test samples. Sample processing may be affected by current workload, re-enforcing the need for discussion with the CRU prior to sending samples for testing.

5 Result Reporting

The full contact details (name, address, phone number) of the single named individual who is responsible for purchasing CRU services must be provided on the submission form.

Results are issued to the submitting laboratory by email to a generic email address which should be provided on the submission form.

Results may also be copied by post or email to the appropriate Health Protection Team in the case of an outbreak or incident involving public health investigations.

Urgent results will be telephoned.

Security Data Protection and Confidentiality:

For the purposes of data protection the Purchaser and CRU should be considered joint holders of the information and hold joint responsibility for ensuring its security in all systems.

The CRU will adhere to the procedures and guidelines implemented to ensure the physical security of all data held within the organisation.

The Purchaser may at any time request access to the CRU (Public Health Wales) policy documents on data protection and information governance.

All data and information belonging to the Purchaser and in the possession or control of the CRU will be held under secure conditions and treated as confidential. With the exception of named officers the CRU will not disclose data to any third party without prior consent of the Purchaser. The CRU will ensure that the guidelines contained in its policy statements entitled "Guidance on disclosure of Personal Data" and "Document Storage and Retention" will be adhered to at all times.

Public Health Wales reserves the right to disclose information obtained in the course of delivering this agreement to proper authorities specifically in the interest of Public Health Wales' public health functions and such information may also be utilised anonymously for epidemiological purposes.

Appendix 1



GIG
CYMRU
NHS
WALES

Iechyd Cyhoeddus
Cymru
Public Health
Wales

Cryptosporidium Reference Unit
Public Health Wales Microbiology
Singleton Hospital, Swansea SA2 8QA
Tel: 01792 285341

Submission Form 3 v7 *Cryptosporidium* genotyping from water testing slides
for use with "User guide for the submission and acceptance of *Cryptosporidium* slide
genotyping" (CRUGUID 100)

Please complete both pages, email in advance to Swansea.Crypto@wales.nhs.uk
& enclose with slides

Lab. name: _____ PO number: _____

Your name: _____ Signature: _____

Address: _____

Postcode: _____ Tel: _____

Generic email address for receipt of results: _____

Section A: Investigation details and service required

Event or investigation reference: _____

Client Water Company: _____

The *Cryptosporidium* slide genotyping service required (please tick one):

The monthly service, for operational or event management

Urgent investigation of a public health emergency (results may be copied to public health authorities). If ticked, please provide investigating Local Authority or Health Protection Unit: _____

Section B: Your reagent details (it is important that you supply the product code; samples may be rejected if not compatible with slide genotyping)

FITC stain: _____ Product code: _____

Mountant: _____ Product code: _____

Section C: Sample submission details

Date sent to CRU: _____

Transport by: Royal Mail Special Delivery / Courier: _____

Tracking number: _____

CRU use only

Received by: _____ Condition: _____

Signature: _____ Date/Time stamp: _____

Appendix 2: Public Health Wales' Food, Water and Environmental Service (FWES)

TERMS AND CONDITIONS OF BUSINESS

1. APPLICATION

1.1 These Terms and Conditions will apply and be incorporated into every agreement for the provision of services by Public Health Wales FWES (the Supplier") to any customer ("the Customer"). They shall apply over any other terms or conditions, (whether or not in conflict or inconsistent with these Terms and Conditions), contained or referred to in any documentation submitted by the Customer or in correspondence or elsewhere or implied by trade custom, practice or course of dealing unless specifically excluded or varied in writing by an authorised representative of Public Health Wales and any purported provisions to the contrary are hereby excluded or extinguished.

1.2 A request by the Customer for performance of testing services shall (without prejudice to Condition 2 or any other manner in which acceptance of these Terms and Conditions may be evidenced) be deemed to constitute unqualified acceptance of these Terms and Conditions.

1.3 If, subsequent to any agreement which is subject to these Terms and Conditions, an agreement for the provision of services is made with the same Customer without reference to any terms and conditions of sale and/or supply, such agreement howsoever made shall be deemed to be subject to these Terms and Conditions.

2. QUOTATIONS AND ACCEPTANCE

2.1 A quotation by Public Health Wales does not constitute an offer and Public Health Wales reserves the right to withdraw or revise a quotation at any time prior to the Public Health Wales' acceptance of the Customer's order or request for services.

2.2 Public Health Wales' acceptance of the Customer's order (including telephone orders) shall be effective only where such acceptance is in writing and signed by an authorised representative of Public Health Wales and sent to the Customer by Public Health Wales. For the purposes of ad hoc sample testing, the request form may constitute the Customer's order and a Public Health Wales' signature of receipt considered as acceptance of that order.

2.3 Public Health Wales reserves the right to perform its obligations under these Terms and Conditions regarding the provision of services at any of its laboratories notwithstanding any representations made to the Customer that such work would be carried out at a specified laboratory.

3. PRICES

The prices payable for services shall be those set out in Public Health Wales' contract and/or order acknowledgement and shall be exclusive of VAT and any other tax or duties payable by the Customer. Public Health Wales shall have the right, upon thirty days' written notice to the Customer, to withdraw any discount from its normal prices and to revise prices to take account of inflation and/or

increases in costs including (without limitation) costs of any materials, carriage, labour or overheads, the increase or imposition of any tax, duty or other levy and any variation in exchange rates.

4. TERMS OF PAYMENT

Payment of invoices must (unless otherwise specified by Public Health Wales) be made in full within 30 days. Unpaid amounts may be subject to interest and any other charges incurred by the Public Health Wales as a consequence of pursuing payment. Public Health Wales reserves the right to suspend the provision of services to the Customer where any amounts are overdue under any contract with the Customer until all such amounts have been paid. For ad hoc test requests, payment may be made with the order/request to work. Cheques should be made payable to 'Public Health Wales NHS Trust'.

5. DELIVERY OF SERVICES

5.1 Turnaround times quoted or otherwise published elsewhere for the performance of the services mentioned in any quotation are approximate only and not of any contractual effect. Public Health Wales shall not be liable to the Customer in respect of any failure to deliver or perform on any particular date or dates, and the Customer shall have no right to terminate any contract to which these Terms and Conditions apply through such failure or failures.

5.2 The Customer shall be solely responsible for delivery of samples to the Public Health Wales premises unless otherwise stipulated by or agreed with Public Health Wales. Public Health Wales may arrange for collection of samples on behalf of the Customer; this will be subject to an additional charge which will be quoted and agreed with the Customer as part of the order for testing.

5.3 Any samples or other property of the Customer in or under Public Health Wales' possession or control and all property supplied to the Public Health Wales on behalf of the Customer remains the property of the Customer.

6. WARRANTY

6.1 Public Health Wales warrants that all services will be supplied in accredited laboratories in accordance with appropriate professional, technical and quality standards. Tests will be performed using recognised national standard methods where available. If Public Health Wales receives written notice from the Customer of any breach of this warranty within 30 days of receipt of the services by the Customer, then Public Health Wales shall, at its option, re-perform the services in questions and/or refund the cost of such services to the Customer.

6.2 Public Health Wales shall not be obliged to rectify any problem caused by fair wear and tear, abnormal or unsuitable conditions of storage or use or any act, neglect or default of the Customer or of any third party.

6.3 Public Health Wales reserves the right not to test samples or conduct analysis on any materials which it deems to be unsuitable for such work. Any failure or refusal to test such samples or materials shall not constitute a breach of these Terms and Conditions. Public Health Wales shall refund any price received in connection with the relevant proposed test or analysis subject to Public Health Wales' costs in connection with the relevant proposed test, analysis or materials.

7. LIABILITY

7.1 Nothing in these Terms and Conditions shall operate to exclude or restrict Public Health Wales' liability for fraud, or any other types of liability which cannot by law be excluded or restricted.

7.2 Public Health Wales' aggregate liability to the Customer whether for negligence, breach of contract, misrepresentation or otherwise shall in no circumstance exceed the price paid by the Customer for the services supplied to it by Public Health Wales under these Terms and Conditions.

7.3 Public Health Wales shall not be liable to the Customer, whether for negligence, breach of contract, misrepresentation or otherwise, for (a) loss or damage incurred by the Customer as a result of third party claims; (b) loss of profit, goodwill, reputation, business receipts, contracts, business opportunity or anticipated saving suffered by the Customer; or (c) indirect or consequential loss or damage suffered by the Customer.

7.4 Except as set out in these Terms and Conditions, all conditions, warranties and representations, expressed or implied by (i) statute, (ii) common law or (iii) otherwise, in relation to the services supplied by Public Health Wales are excluded.

8. CONFIDENTIALITY

8.1 Subject to Clauses 8.2 and 8.3, Public Health Wales agrees to treat as confidential any information in respect of or arising from the provision of to the Customer under a contract to which these Terms and Conditions apply. This obligation shall not apply where the information so arising is, at the date of the agreement covered by these Terms and Conditions, publicly known, or subsequently becomes publicly known, other than by Public Health Wales' breach of these Terms and Conditions or can be shown by Public Health Wales to have been known by it before disclosure by the Customer to Public Health Wales or is required by law to be disclosed.

8.2 Public Health Wales is required to pass on to the appropriate authority any information it deems necessary to safeguard Public Health. Public Health Wales reserves the right to disclose such information obtained in the course of this Agreement. Wherever possible the Customer will be advised of this disclosure. Public Health Wales may use information generated in the course of this agreement for epidemiological purposes usually in anonymised and aggregated form.

8.3 Public Health Wales may disclose any information it is required to disclose by order of a court or other public body that has jurisdiction over it, including, but not limited to, the Information Commissioner and the Information Tribunal. Public Health Wales may also disclose any information which it reasonably believes it is required to disclose under the Freedom of Information Act 2000 or under the Environmental Information Regulations 2004.

8.4 Any report or analysis produced by Public Health Wales arising from work carried out by Public Health Wales shall be presented to the Customer solely for the purpose for which it was commissioned. All intellectual property rights, including, without limitation, copyright, in any such report or analysis, and all

such rights in the name and marks of or used by Public Health Wales, vest in Public Health Wales, and such report, analysis, marks and names shall not be used by the Customer for any purpose including, without limitation, advertising, customer information, publicity, litigation or negotiation with any third party unless expressly agreed with Public Health Wales prior to the production of such report or analysis.

8.5 The Customer shall treat as confidential all other information which it receives from Public Health Wales which shall include, without limitation, information regarding Public Health Wales' products, operations, processes, plans or intentions, product information, know-how, design rights, trade secrets, market opportunities, business affairs and methods, testing procedures, and laboratories.

9. DATA PROTECTION

In performing their respective obligations under any contract to which these Terms and Conditions apply, each party shall comply with the Data Protection Act 1998 and any other applicable data protection or privacy legislation in any relevant jurisdictions.

10. FORCE MAJEURE

Public Health Wales shall not be liable to the Customer for any loss or damage which may be suffered by the Customer as a direct or indirect result of the supply of services by Public Health Wales being prevented, hindered, delayed, cancelled or rendered uneconomic by reason of circumstances or events beyond Public Health Wales' reasonable control ("force majeure circumstances") which include, without limitation, strike, lock-out, labour dispute, act of God, war, riot, civil commotion, malicious damage, compliance with a law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, fire, flood and/or storm. In force majeure circumstances Public Health Wales may in its sole discretion terminate any contract to which these Terms and Conditions apply, and which is so affected by such force majeure circumstances, with immediate effect by written notice to the Customer or postpone performance of service until such force majeure circumstances no longer exist.

11. TERMINATION

Public Health Wales may, without prejudice to any of its other rights, stop or suspend services to the Customer and/or terminate any contract to which these Terms and Conditions apply with immediate effect by written notice to the Customer if (a) the Customer is in breach of an obligation under such a contract; or (b) the Customer passes a resolution for its winding up or a court of competent jurisdiction makes an order for the Customer's winding up or dissolution, or an administration order is made in relation to the Customer, or a receiver over an asset of the Customer is appointed, or an encumbrancer takes possession of or sells an asset of the Customer, or the Customer makes an arrangement or composition with creditors generally or makes an application to a court of competent jurisdiction for protection from its creditors generally, or anything analogous to any of the foregoing events occurs under the laws of any applicable jurisdiction.

11.2 Upon termination of any contracts pursuant to Clause 10.1 or 11.1, any indebtedness of the Customer to Public Health Wales shall become immediately due and payable and Public Health Wales shall be relieved of any further obligation to perform any services to the Customer pursuant to such contracts.

11.3 The Customer may, with 14 days' written notice, terminate any contract with Public Health Wales within 14 days of receiving notice of any increase in price as described in Clause 3 above and which is relevant to the contract in question.

11.4 Each party's further rights and obligations cease immediately on termination of the contract subject to these Terms and Conditions, but termination does not affect a party's accrued rights and obligations at the date of termination.

12. WAIVER

Failure by Public Health Wales to exercise or delay by Public Health Wales in exercising any right or remedy provided by any contract to which these Terms and Conditions apply or by law shall not constitute a waiver of that right or remedy or any other rights or remedies and no single or partial exercise of any right or remedy shall prevent any further exercise of that right or remedy or the exercise of any other right or remedy.

13. GOVERNING LAW

Any contract to which these Terms and Conditions apply shall be governed by, and construed in accordance with, laws.

14. DISPUTE RESOLUTION

14.1 If there is any dispute between the parties arising from or in connection with any contract subject to these Terms and Conditions, either Public Health Wales or the Customer may serve on the other a written Notice of Dispute specifying the dispute and requesting that the parties use their best endeavours to resolve it. If a Notice of Dispute is served by one party, the other may within 14 days serve its own Notice of Dispute. The Parties shall use their best endeavours to seek during the 30 days following service of the first Notice of Dispute to resolve through negotiation in good faith the dispute(s) specified in the Notice(s) of Dispute.

14.2 If the dispute is not resolved in accordance with Clause 14.1 above within 30 days of service of the first Notice of Dispute, the dispute may be referred to the Centre for Effective Dispute Resolution in London ("CEDR") for mediation in accordance with CEDR's procedures for the time being so far as not inconsistent with this paragraph. If the parties are not able to agree on any aspect of the procedures for the mediation, including, without limitation, the identity of the mediator, it shall be decided by CEDR or, if CEDR so determines, by the mediator.

14.3 If a dispute is not resolved by the processes referred to in Clauses 14.1 and 14.2 above, within 120 days of service of the first Notice of Dispute, the parties hereby submit to the exclusive jurisdiction of the UK Courts in relation to any dispute arising from or in connection with any contract subject to these Terms and Conditions.

14.4 Neither Public Health Wales nor the Customer may commence legal proceedings, whether in Wales or elsewhere, arising from or in connection with any contract subject to these Terms and Conditions for 120 days from service of the first Notice of Dispute. Either party may, however, seek urgent interlocutory relief from the Courts before the expiry of that period. Public Health Wales and the Customer shall only take those steps necessary to obtain or to challenge the grant or continuation of that relief and save as aforesaid shall otherwise still be required to act in accordance with this clause as if no application for interlocutory relief had been made.

15. ENTIRE AGREEMENT

These Terms and Conditions, together with the specification of the services set out in the Public Health Wales' order acknowledgement, constitute the entire agreement under which the services specified in Public Health Wales' order acknowledgement are supplied by Public Health Wales to the Customer, and supersede all prior agreements or understandings between Public Health Wales and the Customer in relation to the transaction contemplated hereof.

16. NOTICES

16.1 Subject to Clause 14, a notice under or in connection with a contract to which these Terms and Conditions apply shall be in writing and shall be delivered personally or sent by first class post pre-paid recorded delivery (and airmail if overseas) or by fax to the party due to receive the notice at its last known address.

16.2 Unless there is evidence that it was received earlier, a notice is deemed given (a) if delivered personally, when left at the address referred to in Clause 19.1; (b) if sent by post, except airmail, two days after posting it; (c) if sent by airmail, six days after posting it; and (d) if sent by fax, on completion of its transmission.

17. GENERAL

17.1 The invalidity, illegality or unenforceability of the whole or any part of a condition does not affect or impair the continuation in force of the remainder of these Terms and Conditions.

17.2 The Customer may not assign or transfer or purport to assign or transfer any of its rights or obligations under a contract to which these Terms and Conditions apply without first having obtained Public Health Wales' written consent.

17.3 A person who is not a party to a contract to which these Terms and Conditions apply has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of that contract but this does not affect any right or remedy of a third party which exists or is available apart from that Act.