SERVICE GUIDE

Clinical Extraction Service

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1300 247 301
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SVG2211CEXT

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1.0 Overview

AGRF utilises Qiagen's magnetic-particle technology to ensure high-quality, efficient extraction of DNA from a variety of human derived samples. Our automated system allows for rapid processing of urgent clinical samples for use in accredited clinical downstream processing. Paired with our integrated Laboratory Information Management System (LIMS), and with support from qualified and experienced staff, our clinical extraction service provides a National Association of Testing Authorities (NATA) accredited add-on to other clinical offerings from AGRF including constitutional cytogenetics, whole genome sequencing, complex disease studies and translational research.

Our clinical extraction service has been developed to accept submissions of:

- Whole blood
- Oral fluids / swabs
- Formalin-fixed, paraffin embedded (FFPE) samples (slides or scrolls)

AGRF is a NATA-accredited Medical Testing laboratory to the ISO15189 standard, offering a wealth of knowledge and expertise to produce the highest quality DNA for use in downstream applications.

AGRF offers the following downstream clinically accredited services:

- Illumina array-based genotyping services
  - Constitutional cytogenetics
  - Complex disease studies using Illumina Global Screening Array and Global Diversity Array
- Illumina next-generation sequencing services
  - Whole Genome Sequencing
  - Whole Exome Sequencing
- Clinical variant confirmation service
  - Confirmation of SNVs and small indels using Sanger sequencing

2.0 Sample Submission Requirements

AGRF can accept samples in the following formats with the corresponding requirements:

Whole blood

- At least 500 µl of whole blood in a PAXgene tube or a blood collection tube treated with EDTA (purple cap) or ACD (yellow cap).
- Instructions and guidelines for sample handling and storage of blood collection tubes provided by the manufacturer should be followed.
- For short-term storage (within 48 hours of collection), blood collected in tubes containing anticoagulant may be stored at 2–8°C. For long-term storage (> 48 hours after collection), blood collected in tubes containing anticoagulant may be stored at −70 to −80°C.
- Collection tubes containing samples can be submitted fresh on cold packs within 24 hours of collection or frozen on dry ice.

Oral fluid, as saliva or buccal swabs

- Saliva should be collected using DNA Genotek ORAgene DNA collection kits (e.g. OG-600) and buccal swabs should be collected using DNA Genotek ORAcollect DNA collection kits (e.g. OCR-100), following manufacturer's instructions.

- For storage, oral fluid collected in ORAgene and ORAcollect collection tubes should be stable at ambient temperature for 30 days.
- Collection tubes containing samples can be submitted at ambient temperature. DNA yield from oral fluid may vary significantly between donors or when collected at different timepoints from the same donor.

FFPE material

- FFPE samples should be provided preferably as 5 – 10 µm scrolls in tubes, or mounted sections on slides
- 1 - 4mm^3 of tissue, excluding the area of paraffin, should be provided. This is calculated from the approximate surface area of tissue, the number of sections and the thickness of sections (Figure 1 and Table 1).

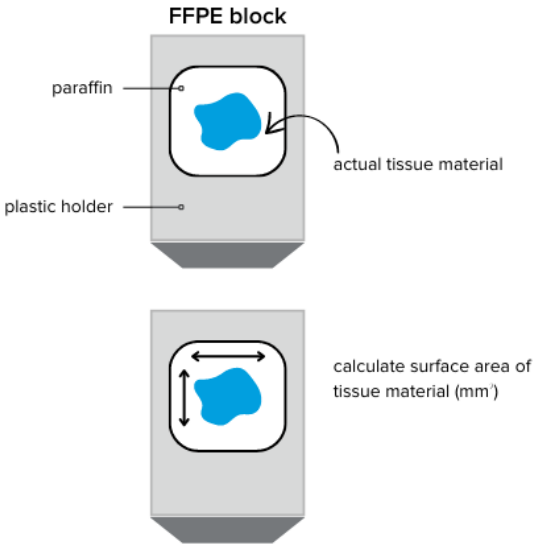

Figure 1. Calculation of surface area of tissue material

Table 1. Calculation of total volume.

Surface Area	Number of Sections	Total Volume
50 mm^2	1	0.5 mm^3
	2	1 mm^3
	4	2 mm^3
	8	3 mm^3
100 mm^2	1	1 mm^3
	2	2 mm^3
	4	3 mm^3
200 mm^2	1	2 mm^3
	2	4 mm^3
400 mm^2	1	4 mm^3

- In cases where calculating the amount is impossible, please provide 10 sections of 5 µm thickness or an equivalent volume.
- DNA yield and quality from FFPE samples varies greatly, depending on the tissue type, fixation and embedding conditions, as well as storage period and conditions.

Use of poor-quality starting material, and/or improper handling and storage of samples may lead to reduced quality and yield of purified nucleic acids, which may impact downstream data quality.

3.0 Turnaround Time

The turnaround time expected for sample processing will depend on the downstream application selected for your clinical samples. Our clinical extraction service is an add-on to our downstream applications and not a stand-alone service, and regular updates will be provided for clients as samples reach milestones.

The first milestone reporting point is on sample receipt, with a second reporting point at delivery of the DNA QC report. This has a typical turnaround time of 2 business days from sample receipt.

4.0 Sample Storage

Extracted DNA and excess raw sample material will be stored at AGRF for three months after you receive your data from any downstream clinical application.

If you wish to have your extracted DNA samples returned, please discuss this with your Account Manager during quoting, or once you have received your data. At the completion of your project, we can either:

- Return extracted DNA samples by courier at ambient temperature; or
- Return extracted DNA samples by courier on dry ice

Return or destruction of excess unextracted sample material should be discussed with your Account Manager.

Please contact AGRF for a quote for sample returns by phone (1300 247 301) or by email (CustomerCare@agrf.org.au). If we are not notified within the specified three-month time frame, samples will be automatically destroyed.

5.0 Shipping Your Samples for Extraction

Blood and saliva must be shipped to AGRF packaged and labelled appropriately for transport of Biological Substances, Category B (UN3373). FFPE samples should be packaged to ensure slides arrive unbroken, preferably in slide cases or similar.

Physical address (couriers)
AGRF MELBOURNE
VCCC LOADING DOCK*
14 FLEMINGTON ROAD
NORTH MELBOURNE VIC 3051

Address for sample drop off:
AGRF MELBOURNE
LEVEL 13, VICTORIAN COMPREHENSIVE CANCER CENTRE
305 GRATTAN STREET
MELBOURNE VIC 3000

* Note that our loading dock is open from 8am to 4pm weekdays

6.0 Online Sample Submission

- Log in to MY AGRF HUB and click on “Submit your Samples”.
- If you have more than one Agreement, select the relevant Agreement ID from the drop-down list, which will match the number portion of the Quote ID generated by your Account Manager.
- Complete and upload the sample ID template file. Two unique sample identifiers are required and these need to match those on the sample tube(s), or slide(s) provided.
- Submit the form and print a copy of the submission receipt to be included with your sample package.
- If submitting multiple sample material types, multiple submissions will need to be completed.

AGRF is committed to handling personal information (including health information and other sensitive information) in accordance with all applicable privacy laws, including the Australian Privacy Principles set out in the Privacy Act 1988. AGRF’s Privacy Policy is available on its website or upon request. AGRF provides clear instructions on handling confidential information and details the various security measures that must be followed for such information.

By submitting samples and requesting a clinical genomics service you agree you have the informed consent of the individual being tested and can produce the signed consent form if requested or the approval from the relevant Human Research Ethics Committee (HREC) the work is being conducted under.

7.0 Quality Statement

All works carried out by AGRF are performed following the strict requirements of ISO15189. AGRF Ltd is accredited as a Medical Testing laboratory according to the ISO15189 standard by the National Association of Testing Authorities. Staff follow Standard Operating Procedures, which define their responsibilities and provide guidance on achieving standards; compliance is monitored at regular reviews and internal audits. All work is supervised by a person with relevant qualifications and was checked while in progress and upon completion to ensure that it meets the necessary ISO15189 standards.