ASSESSMENT INFORMATION DOCUMENT

Your facility is due for a reassessment.

This Assessment Information Document seeks specific background information from **ACCREDITED FACILITIES** on the current scope of NATA accreditation, any changes required, and the specific resources available to meet the requested changes.

Some sections may not apply to your facility. Please cross-reference relevant sections from your management system documentation where appropriate.

Please return a completed copy of this Assessment Information Document and required documents/records as detailed in covering letter to:

s22 [redacted]

If you have access, the documents can be uploaded to the Members Portal. If you do not have access to the Members Portal you can apply at the NATA website (https://myportal.nata.com.au/). Delays or failure to provide the requested information may result in delays to the accreditation process.

The personal information collected in this document and other management system documentation supplied for the assessment briefing is used for conducting the assessment, reporting on the assessment and the process of continuing accreditation. It may be disclosed to NATA staff members, all of whom have signed confidentiality agreements. Aggregated data gathered from the assessment process may also be provided to third parties in a de-identified format. It may also be disclosed to agencies to which NATA has a legal obligation or with which NATA has formal agreement.

Personal information collected such as name, business telephone and mobile phone numbers and email address of the Authorised Representative or the Site Contact may be made available to enquiries requiring the service of NATA accredited facilities. The Site Contact details may be included in the NATA website directory.

NATA's Privacy Policy contains information on access and correction to the personal information held by NATA and the compliant process associated with breaches of the Australian Privacy Principles. NATA's Privacy Policy is available from the NATA website, www.nata.com.au.

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 2432 Site No: 2425 Job No: TBA

FACILITY DETAILS

In preparation for the accreditation activity, please review the information below to confirm (or change) the details of your facility and the site to be assessed. Use the shaded boxes to provide corrected or changed details.

FACILITY (the name in which accreditation is held)	
Accreditation No: 2432	
Facility Name: Therapeutic Goods Administration	
Facility Trading Name (see note 1):	
ABN or ACN: 40-939-406-804	
Mailing Address: PO Box 100 CANBERRA ACT 2601 AUSTRALIA	
Street address (if different from above): 136 Narrabundah Lane SYMONSTON ACT 2609 AUSTRALIA	
Facility web address (optional): www.tga.gov.au	
Phone: s22 [redacted]	
INVOICING DETAILS (for all sites under your facility)	
Mailing address: 136 Narrabundah Lane SYMONSTON ACT 2609 AUSTRALIA	
Phone:	
Email: s22 [redacted]	

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 2432 Site No: 2425 Job No: TBA

The following details are specific to your Facility's Authorised Representative. (The rights and responsibilities of the Authorised Representative are outlined in the *General Accreditation Criteria: Responsibilities of authorised representatives*, available on the NATA website.)	
Authorised Representative: Dr Lisa Kerr	To change the appointed Authorised Representative please complete the "*Facility Details Update (FDU)*" form available from the NATA website.
Position: Laboratories Branch Assistant Secretary	
Direct Phone:(02) 6289 2132	
Email: lisa.kerr@health.gov.au	
SITE DETAILS	
Site No: 2425	
Site Name: Laboratories Branch Biomaterials & Engineering	
Site Trading Name (see note 1)**:** Therapeutic Goods Administration	
Availability of services: Services conditionally available to external clients	☐ Services available to external clients ☒ Services conditionally available to external clients ☐ Services not available to external clients
Street address (physical location): 136 Narrabundah Lane SYMONSTON ACT 2609 AUSTRALIA	
Site Contact (full name including title): Quality Manager s22 [redacted]	
Phone:	
Mobile: s22 [redacted]	
Indicate the Site Contact's primary contact number: ☐ Phone ☒ Mobile ☐ Other:	
Email: TGA.Laboratories.Quality.System@health.gov.au	

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 2432 Site No: 2425 Job No: TBA

Do you wish to publish the Site contact information on NATA's website directory?

☐ Yes ☒ No

(The name of the contact person and preferred phone number and email address will be listed in our records as the person to contact with enquiries about the Site's activities (i.e. from potential clients) and may be listed on the NATA website.)

Note 1: Trading name(s) (optional)

Providing this information indicates the applicant is seeking approval to issue reports in its trading name(s), in addition to the name of the Facility. Trading names may be provided for a Facility and/or for individual Sites.

In order to able to issue reports in a trading name the following criteria need to be met.

- There must be a clear and reasonable link between the name of the Facility and the trading name(s) supplied, such as an ownership link or a link by virtue of a registered trading name;
- Activities reported in a trading name(s) will have been performed by the staff of the accredited Facility/accredited Site to which the trading name(s) applies, using the same techniques and procedures s those covered by the Scope(s) of Accreditation of the applicable accredited Facility/accredited Site;
- The scope of reporting applicable to the trading name(s) is the same as or a subset of the Scope of Accreditation of the applicable accredited Facility/accredited Site.

Should trading name(s) be provided you will be contacted to further explore this option.

ASSESSMENT INFORMATION DOCUMENT

Accreditation No: 2432 Site No: 2425 Job No: TBA

NATA SCOPE OF ACCREDITATION

A copy of your current scope of accreditation is attached [D21-3198951].

☒ Annotate this scope to indicate the approximate frequency of all laboratory activities.

Animal health facilities only: please also complete the attached Supplement document.

Additions

Do you wish to request additions to the scope of accreditation? **YES**

Surveillance visit: Additions will not normally be considered during a surveillance visit as such visits will not include a technical assessor. Where requested a decision will be made as to how best to meet the request without compromising the aim and focus of the surveillance visit. Accordingly, a variation visit may be arranged concurrently or as a separate visit once all information concerning the request has been considered. Charges will be incurred to accommodate the variation visit in accordance with NATA's Fee Schedule current at the time. Please be aware that any extensions to scope of accreditation may also result in an increase to your annual membership fees.

Reassessment: Any requests for additional activities to be added to the scope of accreditation as part of a scheduled reassessment will only be accommodated where such requests do not compromise the purpose of the reassessment (to review the existing scope of accreditation to determine ongoing compliance with the accreditation criteria). Where additional resources and time are required to accommodate the request, a concurrent variation visit may be arranged and charges will be levied in accordance with the current Fee Schedule available from the NATA website. Please be aware that any extensions to scope of accreditation may also result in an increase to your annual membership fees.

☒ Yes. Please complete the Appendix. **Animal Health facilities** should complete the Appendix table in the attached Supplement document.

☐ No

If yes, relevant documentation must be submitted in advance of the visit (e.g. proposed scope, calibration or test procedures, verification or validation data, sample worksheet, report example and uncertainty calculations).

Reference any attached documentation in the shaded box below:

1. Current scope of accreditation (D21-3198951)
2. Application for changes to the scope of accreditation

All accreditation programs

- Staff
  - List of all relevant staff, including
    - Qualifications (as necessary) (**Page 10 & 11 on NATA Assessment Information Document**)
    - Training, competency and authorization sign-off records
      - Respirator filter particulate penetration – competency assessment checklist – s22 (D21-2732355)

- Mask testing training record for Mabel Au (D21-2732408]

BiomE Competency – Authorisation Matrix Rev 5 (14.10.2021) [D21-2081133]

Measurement, calibration or inspection procedures

- Non-standard and in-house developed method based on modified NIOSH rapid testing SOP
  - The most recent SOP – Particulate Filtration Efficiency – Rapid Screening – Biome-SOP-35
- BIOME respirator PFE decision making guide (D21-3056973)
- Measurement of Uncertainty (MU) (to follow)
- Validation data
  - Reproducibility between operators (D21-3032263);
  - ATI 100Xs performance validation sheet (D21-2824018)

Equipment

- ATI 100Xs - Verification Report – (D21-3151664)
- ATI 100Xs Specifications / Working Range (D21-3241316)
- Other relevant information
  - PFE test equipment list (D21-3034772)
- Maintenance records
  - ATI 100Xs maintenance (D21-2921476)
  - Post service AUG 21 acceptance check (D21-2925594)
- Calibration/check records
  - ATI 100Xs instrument calibration documents ([D21-3211901] & D21-2927841)
  - ATI 100Xs flowmeter post calibration acceptance check (D21-2631144)
  - ATI100Xs forward light scattering linearity and repeatability test (D21-3032135)
  - Instrument precision and accuracy verification (D21-3032287)

Proficiency testing (PT)

- A summary on TGA participation in interlaboratory study led by NIOSH and interlaboratory comparison led by UK INSPEC is found on **Page 13** in **NATA Assessment Information Document**.

Reports and/or Certificates

- Certificate of Responsible Analyst (D21-32398948)
- Rapid PFE results template (D20-3377358)
- Example of rapid PFE results (D21-2931574)
- Letter Template – Medical Devices – Notice of Compliance Test Pass (D20-3404470)
- Letter Template – Medical Devices – Samples tested under the Regulations – Goods do not comply with applicable requirements (D20-166143)

Deletions

Do you wish to request deletions to the scope of accreditation? (E.g. measurements or calibrations no longer performed or where accreditation is no longer required)

☐ Yes
☒ No

If yes, deletions may be annotated on the scope of accreditation or listed in the shaded box below. Attach a separate page if necessary. Please note that additional information may be requested before the deletion can be confirmed.

Amendments

Do you wish to request any amendments to the scope of accreditation? (E.g. standard method name or version updates, change to Calibration and Measurement Capability (CMC), etc.)

☐ Yes
☒ No

If yes, amendments may be annotated on the scope of accreditation or listed here. Attach a separate page if necessary.

Regulatory requirements applicable to laboratory activities

Are any of your laboratory activities covered by your scope of accreditation subject to, or used by your customers to meet, regulatory requirements? For example, do you test products covered by Consumer Safety Law, WHS regulations, trade measurement, food regulation, etc.?

☒ Yes
☐ No

If yes, please indicate this by annotating the attached copy of your current scope of accreditation specifically identifying the relevant regulation (including regulatory body and/or regulatory ruling), standard or other applicable document as appropriate. For example:

Testing is performed to support regulation of the therapeutic goods industries under the following legislation:

- **Therapeutic Goods Act 1989;**
- **Therapeutic Goods Regulations 1990**

Testing of human specimens

Are any of your laboratory activities covered by your scope of accreditation on human samples?

☐ Yes
☒ No

If yes, please annotate this on the attached scope of accreditation. Note that such testing may be subject to the Therapeutic Goods Administration (TGA) In-Vitro Diagnostic (IVD) medical device Framework and assessed against the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Development and use of In-House In Vitro Diagnostic Medical Devices*.

Sampling

Since your previous assessment, are there changes to any sampling conducted covered by your NATA scope of accreditation?

☐ Yes
☒ No
☐ Not applicable

If yes, please include the necessary information under NATA Scope of Accreditation.

Off-Site Laboratory Activities

Since your previous assessment, has your facility commenced performing laboratory activities off-site, for example, field testing or at clients' premises, and do you require this to be covered by your scope of accreditation?

☐ Yes
☒ No

If yes, please provide brief details and include the necessary information under NATA Scope of Accreditation. Also, provide the appropriate cross-reference to your facility documentation.

Note: Refer to relevant documents in the NATA Accreditation Criteria (NAC) package applicable to your scope of accreditation, available from the NATA website, for any specific requirements for such laboratory activities.

STAFF

In the following spaces provided (or on a separate sheet if is insufficient room), list the current facility staff. Please also indicate whether any staff work on a shift or part-time basis.

Name	Qualifications	Position (Please also specifically identify staff responsible for technical and quality management)	Date started in the facility
Staff – Biomaterials and Engineering Section – October 2021 [TRIM - D20-3336985]			
s22 [redacted]			

s22 [redacted]			

Note: NATA will list individuals in the Report on Assessment where there is a regulatory framework or is covered in a Deed of Agreement, Memorandum of Understanding or other binding agreement with a third party. If this is applicable to any of your laboratory activities, indicate in the table any nominated individuals or changes to nominated individuals who are authorised to release results under such an arrangement, including the arrangement in place. Please provide resumes for any new individuals not previously listed.

ENSURING THE VALIDITY OF RESULTS

Has your facility participated in any proficiency tests, measurement audits or inter-laboratory comparison programs since your last assessment?

Refer to the *General Accreditation Criteria: Proficiency testing* document available from the NATA website for the policy on participation in such programs.

☒ Yes
☐ No

If yes, please provide details in the table below. Records of participation in these programs must be available for review during the NATA assessment, together with details of action taken in response to unsatisfactorily performance.

Name of provider, program and activities undertaken	Frequency of program	Last date of participation
NIOSH N95 Inter-laboratory Study to NIOSH testing procedure TEB-APR-STP-0059 E21-296389 20 x N95 respirators tested with sodium chloride aerosol to determine particulate filtration efficiency. 11 labs in total	Annual	30 June 2021
INSPEC UK ILC 21-038 *Particle filter penetration, sodium chloride aerosol, EN 13274-7* E21-327275 3 x FFP2 respirators tested with sodium chloride aerosol to determine particulate filtration efficiency. 35 labs in total.	Annual	26 July 2021

☒ If yes to the above, please provide a summary of your facility's performance in proficiency testing programs or inter-laboratory comparisons. This should include matrices/analytes covered and any outliers recorded (including actions taken).

NIOSH N95 ILS

The PFE results reported by the TGA were satisfactory and no further action taken [NIOSH's ILS Report D21-30214]. TGA post NIOSH ILS Report Review [D21-3031902] did not find any obvious deficiencies associated with the integrity of measurement.– the results were comparable to the other laboratories .

Whilst TGA had the lowest filter penetration average of 11 laboratories, it also had the tightest precision and lowest UoM. TGA was assigned a Z-score = 1.54 and E_n = 0.98 however, this should viewed in the context of the review and the characteristics of the TSI 8130/A automated filter testers used by the other 10 labs.

INSPEC UK ILC 21-038

TGA post review [D21-3123089] of INSPEC's ILC 21-038 Report – issued 23 Sep 21 [D21-3132521] indicated ILC was successful and no further action needed. TGA Z-score of 0.88 however must be when viewed in the context of the ILC.

Objective of the ILC was to compare results obtained by each participant using their own interpretation of the procedure based upon EN 13247-7:2019 – *Respiratory protective devices, Methods of Test*. 35 x laboratories produced 35 different results using different equipment and setups.

EQUIPMENT

Equipment includes, but is not limited to, measuring instruments, reference standards and analytical systems.

Note: Refer to the *General Accreditation Criteria: Equipment assurance, in-house calibration and equipment verification*, available from the NATA website, for further information.

Please complete the table below (or on a separate sheet if there is insufficient room) indicating whether the equipment is calibrated in-house or externally.

Calibration of equipment is necessary when:

- the measurement accuracy of measurement uncertainty affects the validity of reported results; and/or
- the equipment is required to establish the metrological traceability of reported results.

Where calibration of equipment is deemed not necessary, it is still required that the facility ensure equipment has been verified that it conforms with specified requirements (e.g. method requirements; manufacturer's requirements).

Equipment description	**Calibrated**		
	In-house* (see below)		**Externally**
	Yes	**Procedure** **(as per Methods Manual, national or international standard, etc.)**	**Yes**
Equipment for Respirators – Particle Filtration Efficiency [TRIM - D21-3200416]	**No**		**Yes**

☐ * For facilities performing in-house calibrations: please provide a copy of the test method and statement of capability of each in-house calibration identified above.

SUBCONTRACTING, AGENCY OR FRANCHISING ARRANGEMENTS

Since your previous assessment, does your facility now operate under formal subcontracting, agency or franchising agreement with another organisation which you have not advised NATA of?

☐ Yes
☒ No

If yes, please provide details of the arrangement and the principal organisation.

Note: As per *clause 5.3* the laboratory cannot claim conformity with ISO/IEC 17025 for externally provided laboratory activities on an ongoing basis.

TEST REPORTS, SAMPLING REPORTS AND CALIBRATION CERTIFICATES

☒ Please provide an example copy of a recently completed test report and/or sampling report and/or calibration certificate.

Attachment 3 – EXAMPLE - Certificate of Responsible Analyst [TRIM - D21-2866043]

Attachment 4 – Letter Template – Medical Devices – Notice of Compliance Test Pass [TRIM - D20-3404470]

Attachment 5 – Letter Template – Medical Devices – Samples tested under the Regulations – Goods do not comply with applicable requirements [TRIM - D20-3404474]

Note: Refer to the *General Accreditation Criteria: use of the NATA emblem, NATA endorsement and references to accreditation,* available from the NATA website, for criteria relating to endorsing reports.

PROCEDURES

☒ Please provide a list and copy of all non-standard test or calibration or inspection procedures (including in-house procedures) covered by the scope of accreditation.

- Particulate Filtration Efficiency – Rapid Screening – Biome-SOP-35

☒ Please provide an example of an estimation of measurement uncertainty (MU) and a list of the procedures for which MU estimates have been made.

The MU is currently under development (delays due to lockdown and regulatory testing commitments) however will be submitted in the near future.

Changes to least uncertainties of measurement:

☐ If there are changes to least uncertainties of measurement, provide uncertainty calculations and supporting data for their derivation.

☒ Not applicable. There are no changes to least uncertainties of measurement.

SAFETY

Assessments are conducted by a team comprising of NATA staff and voluntary technical assessors who will need to observe the activities covered by your scope of accreditation. To ensure the safety of the assessment team, please provide the following information on hazards that may be routinely experienced as part of the visit, including any site or field work.

Location	Hazard	Precaution
e.g. Abattoir **e.g. Radiography laboratory**	**Q Fever** **Radiation**	**Vaccination required** **Film badge**
All visitors to sign visitor register at front desk and acknowledge they have read and understand the WHS information sheet (refer to Attachment 6 Work Health and Safety Information Sheet – Visitors [TRIM - D20-3406075]) They will be issued with a restricted access pass and accompanied by a member of TGA staff whilst in the laboratory areas. In the event of an emergency, visitors will follow directions from TGA staff.		
Particle filtration efficiency testing laboratory	Nil	PPE will be supplied to all visiting NATA staff upon arrival (i.e. lab coats and safety glasses). Visitors are requested to wear enclosed footwear whilst in the labs. Lab coats are not to be worn outside laboratory areas.
TGA Symonston ACT	COVID 19	Prior to visitors attending the TGA site Part 1 of the form "TGA Labs Branch COVID Risk Management Record" must be completed.

		Attachment 7 - TGA Laboratories – COVID-19 Risk Management - Policy and Procedures for Visitors [TRIM - D20-952905]

Does your facility, or a site to be visited by the assessment team, have a company alcohol and testing policy which the NATA assessment team would be subject to?

☐ Yes
☒ No

If the NATA assessment team is subject to drug/alcohol testing, please provide a copy of your testing policy, including relevant drug/alcohol limits.

☐ Enclosed
☒ Not applicable

MANAGEMENT SYSTEM

NATA have a copy of your organisation's management system documentation Version provided 2 May 2019. If the version and /or date of issue have changed please: **No change**

☐ Provide a copy of the most current version of your management system documentation.

Or if the charges are considered to be minor in nature:

☐ Summarise the changes in the shaded box below:

QMS is electronic.
BIOME Laboratory Operations Manual

ISO/IEC 17025:2017 requires the facility to implement a management system in accordance with either Option A or Option B.

Option A requires clauses 8.2 to 8.9 of the Standard to be addressed.

Option B requires that a management system to be implemented in accordance with ISO 9001.

Your facility has established a management system in accordance with which option of the standard?

☒ Option A
☐ Option B

If the management system established is in accordance with Option A, it will be assessed against clauses 8.2 to 8.9 of the Standard.

If the management system established is in accordance with Option B, the records to be reviewed on-site by the NATA Lead Assessor may be reduced subject to the following:

1) the management system is certified by a certification body (CB) accredited by JAS-ANZ, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA);

2) the CB's accreditation covers ISO/IEC 17021 Parts 1 and 3. If Part 3 is not specifically listed in the CB's scope of accreditation, then it must be clear that its accreditation covers the certification of Quality Management Systems (QMS) to ISO 9001 (which may be included in the scope of accreditation or other documentation provided by the accreditation body signatory to the IAF MLA);

3) copies of the most recent certification audit report(s) issued by the CB covering your facility's management system in full is (are) provided to NATA;

4) confirmation from the CB of the close out of any non-conformities raised during certification audits is provided to NATA;

5) the certification of the management system covers the laboratory activities proposed to be covered by your NATA scope of accreditation.

Evidence in support of 1) to 5) is requested to be submitted with a copy of your facility's management system documentation. The latter is required to allow the assessment team to familiarise itself with your system. The records to be reviewed on-site will be dependent on the extent of the evidence provided and the extent of the audits performed by the CB.

Should evidence supporting points 1) to 5) not be provided, NATA will assess your management system in accordance with Option A (i.e. clauses 8.2 to 8.9 of the Standard).

(End of Document)

APPENDIX: Additions to the scope of accreditation

Activity (the ***area of testing*** for which the facility is accredited)	**Service** (the ***type of test*** provided. Refer to Note 1 & 4)	**Material / Item / Product** (***what is tested***)	**Determination** (what the 'Material / Item / Product' is ***tested for***)	**Technique** (describes ***how the 'Material / Item/ Product' is tested or sampled***)	**Procedure (as per Methods Manual, national or international standard, etc** Refer to Note 2 & 4)	**Approximate frequency** (No./month)	**Regulatory requirements** (Refer to Note 3)
Example Environment	Analysis for elements	Ground waters; Bore waters;	Lead	Flame/furnace/AAS ICP/AES	APHA (Method 304) In-house (Method 6A)	10 5	
Manufactured Goods	Performance evaluation of personal protective equipment (PPE)	Respiratory protective devices (respirators)	Particle Filtration Efficiency (PFE)	Sodium chloride aerosol	TGA In-house - *Particulate Penetration Efficiency - Rapid Screening* based on NIOSH TEB-APR-STP-0059	20 samples	N/A

Note 1: Refer to the *Specific Accreditation Guidance: Scope of accreditation - Service descriptors* documents in the relevant NATA Accreditation Criteria (NAC) packages available from the NATA website. These documents describe the laboratory activities currently able to be accredited. Where an activity to be accredited is not described in one of these documents, please provide as much information as possible in the table above.

Note 2: For non-standard and in-house developed methods, validation data must be provided.

Note 3: Refer to previous page under “Regulatory requirements applicable to laboratory activities”.

Note 4: For calibration facilities only:

- The ‘Procedure’ column may be used for the inclusion of reference devices providing the entry is not model specific.
- Uncertainty calculations and supporting data must be provided for the derivation of least uncertainties of measurement.
- Please provide on a separate sheet the ranges and uncertainties for each calibration service