

9.Laboratory Services

These forms are designed to be used by both hospital personnel and external surveyors. The following information must be provided after each survey, before submitting the completed survey forms.

information must be provided after each survey, before	submitting the completed survey forms.
1.NAME OF HOSPITAL/CLINIC/FACILITY:	
2. BASELINE/INTERNAL SURVEY INFORMATION:	
Title and name of person who completed this docume	ent:
Post and position held:	
Date of survey:	
3. EXTERNAL SURVEY INFORMATION:	
Name of external surveyor:	
Date of external survey:	
GUIDE TO COMP	PLETION OF FORM
N.B. Hospital staff are please to use BLACK ink at	all times. The external surveyors are requested to
use RED ink at all times.	
Please circle the rated compliance with the criterio (Partially compliant), C (Compliant).	on, e.g. NA (Not applicable), NC (Non-compliant), PC
The default category affected is designated on the each criterion as follows: 1. patient and staff safety 2. legality 3. patient care 4. efficiency 5. structure 6. basic management 7. basic process 8. evaluation The seriousness of the default is designated on the form for each criterion as follows: 1. mild 2. moderate 3. serious 4. very serious	
	Documents Checked Surveyor: Surveyor:

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9.1 Management of the Service

9.1.1 Standard

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Laboratory services are available to meet the needs of services and patients, in compliance with national laws, regulations and standards.

Standard Intent: The organisation has a system for providing the laboratory services, including clinical pathology services, required by its patient population, clinical services offered and healthcare providers' needs.

The laboratory services are organised and provided in a manner that meets applicable national standards, laws and regulations.

Laboratory services, including those required for emergencies, may be provided within the organisation, by agreement with another organisation or both. Laboratory services are available after normal hours for emergencies.

Outside sources are convenient for the patients. The organisation selects outside sources based on the recommendations of the director or other individual responsible for laboratory services. Outside sources of laboratory services meet applicable laws and regulations and have acceptable records of accurate, timely services. Patients are informed when an outside source of laboratory services is owned by the referring medical practitioner.

Laboratory results are validated to ensure that they are those of the correct patient and medical practitioner. Validations include the name of the validating officer.

Results are reported within a time frame based on patient needs, services offered and the needs of the clinical personnel. Emergency tests, after-hours and weekend testing needs are included. Appropriate specimen containers are available in the organisation, with instructions for their correct use.

	Criterion	Comments
		Recommendations
Criterion 9.1.1.1	Adequate, convenient and	
Critical:	regular laboratory services are available to meet the	
Catg: Basic Management + Efficiency	organisation's needs.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.1.1.2	The laboratory services are	
Critical:	organised and provided in a manner that meets applicable	
Catg: Basic Management + Legality	national standards, laws and	
Compliance	regulations.	
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 9.1.1.3	Emergency laboratory	
Critical:	services are available, including after-hours services.	
Catg: Basic Management + Patient Care	interesting area mode out vioca.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.1.1.4	The organisation has	
Critical:	established the expected report time for results.	
Catg: Basic Process + Efficiency	Toport anno for roduitor	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 2 Moderate		
Criterion 9.1.1.5	Laboratory results are	
Critical:	reported within a suitable time frame to meet patient needs.	
Catg: Basic Process + Efficiency	marile to meet patient needs.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 2 Moderate		
Criterion 9.1.1.6	Laboratory results are	
Critical: D	validated and include unique	
Catg: Basic Management + Pat & Staff Safety	patient identity, date of testing/reporting, name and location of the requesting	
Compliance	medical practitioner.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.1.1.7	The validating officer is	
Critical:	identified and recorded.	
Catg: Basic Management + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 2 Moderate		

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Criterion 9.1.1.8 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 2 Moderate	A list of referral laboratories which have been duly approved is available for tests not performed on site.	
Criterion 9.1.1.9 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious	There is a documented, implemented procedure for packaging specimens and transporting them to the referral laboratories.	
Criterion 9.1.1.10 Critical: Catg: Basic Process + Legality Compliance NA NC PC C Default Severity for NC or PC = 3 Serious	A register is kept of the referred specimens and the results.	

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9.1.2 Standard

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A qualified individual is responsible for managing the laboratory service.

Standard Intent: The laboratory service is under the direction of an individual who is qualified by virtue of documented training, expertise and experience, in accordance with applicable laws and regulations. This individual has professional responsibility for the laboratory facility and for the services provided. When this individual provides clinical consultations or medical opinions, he/she is a medical practitioner or a pathologist. Speciality and subspecialty laboratory services are under the direction of appropriately qualified individuals. The responsibilities of the laboratory director include:

- developing service-related policies and procedures and ensuring that they are implemented and reviewed regularly
- managing relevant human resource functions, e.g. job descriptions, personnel evaluation, personnel training, and
- developing, coordinating and monitoring the required quality control and improvement systems.

Criterion Comments		Comments
		Recommendations
Criterion 9.1.2.1 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious	The laboratory is under the direction of a qualified individual.	TOOGHINGHAUNIS
Criterion 9.1.2.2 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 4 Very Serious	The responsibilities of this person include maintaining quality control programmes.	
Criterion 9.1.2.3 Critical: Catg: Basic Management + Efficiency Compliance NA NC PC C Default Severity for NC or PC = 3 Serious	The responsibilities of this person include administrative supervision.	

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Criterion 9.1.2.4	The responsibilities of this	
Critical:	person include monitoring and reviewing all the	
Catg: Evaluation + Efficiency	laboratory services.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

9.1.3 Standard

Individuals with adequate training, skills, orientation and experience perform tests and interpret the results.

Standard Intent: The organisation identifies the laboratory personnel who may perform testing and who may direct or supervise testing. Supervisory and technical personnel have appropriate and adequate training, experience and skills and are oriented to their work. Technical personnel are given work assignments consistent with their training and experience. In addition, there are enough staff members to perform laboratory tests promptly and to provide the necessary laboratory services during all hours of operation and for emergencies.

The organisation is able to identify and contact experts in specialised diagnostic areas, such as parasitology or virology, when needed.

	Criterion	Comments
		Recommendations
Criterion 9.1.3.1	Qualified individuals are	
Critical:	assigned to perform and supervise the provided	
Catg: Basic Management + Efficiency	laboratory services.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.1.3.2	There are enough staff	
Critical:	members to meet service needs.	
Catg: Basic Management + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 9.1.3.3	On-going in-service training is provided to all personnel.	
Catg: Basic Management + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.1.3.4	Records of the training	
Critical:	provided are kept for each staff member.	
Catg: Basic Management + Efficiency	otali mombol.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 2 Moderate		

9.2 Facilities and Equipment

9.2.1 Standard

Laboratory buildings are adequate to provide a safe and effective laboratory service.

Standard Intent: Departmental managers need to work closely with organisational managers to ensure that facilities and equipment are adequate. Departmental managers keep organisational managers informed about inadequate facilities, additional equipment requirements and the current state of facilities and equipment.

The general state of the laboratory will be checked. The walls, floor and ceiling should be in a good condition. As few items/instruments as possible should be placed on the floor.

	Criterion	Comments
		Recommendations
Criterion 9.2.1.1	The laboratory is a separate	
Critical:	designated area within or in close proximity to the health	
Catg: Basic Management + Physical Struct	facility.	
Compliance	1	
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 9.2.1.2	The size of the laboratory is	
Critical:	appropriate to the services provided.	
Catg: Basic Management + Physical Struct		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.2.1.3	The ceiling and walls are	
Critical:	clean and painted in a light colour.	
Catg: Basic Management + Physical Struct	oloui.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.2.1.4	The floor has a smooth and	
Critical:	continuous surface.	
Catg: Basic Management + Physical Struct		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.2.1.5	The ceiling is not leaking and	
Critical:	does not show signs of moisture.	
Catg: Basic Management + Physical Struct	moistare.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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9.2.2 Standard

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Laboratory fixtures and fittings are adequate to provide a safe and effective laboratory service.

Standard Intent: The laboratory has to be constructed in such a way that it can provide the projected laboratory services. The laboratory has to have sufficient and proper laboratory benches, washing and staining facilities, sufficient power and water requirements and preferably a controlled temperature. The following specific details should be monitored:

- Laboratory benches and equipment should be of a material that can support the laboratory instruments (strong) and should be of a material that cannot affect the surface of the table. Preferably the laboratory tables are constructed of concrete that is tiled. No wooden tables are allowed.
- At least one washing unit is available for standard cleaning and washing activities.
 When staining is performed, two units are preferred.
- The number and quality of the available electrical sockets should be sufficient for the projected activities.
- The water supply should be guaranteed to provide washing and staining activities.

	Criterion	Comments
		Recommendations
Criterion 9.2.2.1	There are sufficient laboratory	
Critical:	benches for the projected activities.	
Catg: Basic Management + Pat & Staff Safety	don vinos.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.2.2.2	Laboratory benches are	
Critical:	strong enough for the projected activities (e.g. large	
Catg: Basic Management + Pat & Staff Safety	instruments).	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.2.2.3	There is either an	
Critical:	uninterrupted power supply (UPS), battery backup system	
Catg: Basic Management + Pat & Staff Safety	and/or an automated voltage stabilizer (AVS) present for	
Compliance	critical equipment.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 9.2.2.4	Each laboratory compartment	
Critical:	has adequate ventilation, with room temperature below	
Catg: Basic Management + Pat & Staff Safety	25°C, and a temperature record is kept.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

9.2.3 Standard

There is sufficient laboratory equipment that is adequate to provide a safe and effective laboratory service.

Standard Intent: In order to provide effective laboratory services, it is essential that specific equipment is available. Laboratory management and personnel are responsible for the selection and availability of the critical instruments, their operation according to manufacturer's instructions and their appropriate maintenance. The following aspects must be considered:

- Processes for the selection and procurement of new instruments
- The availability of an equipment inventory management system
- The maintenance of the available equipment through inspection, testing and calibration
- Monitoring of and acting on equipment hazard notices, recalls, reportable incidents, problems and failures
- The availability of a system where activities are documented.

Testing, maintenance and calibration frequencies are related to the laboratory's use of equipment and its documented history of service.

	Criterion	Comments
		Recommendations
Criterion 9.2.3.1	Sufficient equipment is	
Critical:	available to provide the required laboratory services	
Catg: Basic Management + Efficiency	for the projected activities.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.2.3.2	All equipment is in good	
Critical:	working order and is operating appropriately.	
Catg: Basic Management + Efficiency	poporating appropriatory.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 9.2.3.3	Records are maintained to	
Critical:	indicate that all equipment is regularly inspected,	
Catg: Evaluation + Efficiency	maintained and calibrated.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

9.3 Reagents, Chemicals and Kits

9.3.1 Standard

The supplies of laboratory consumables, reagents, chemicals and kits are adequate to provide a safe and effective laboratory service.

Standard Intent: The organisation has identified those reagents and supplies needed to regularly guarantee the laboratory services provided to its patients. There is an effective process for ordering and ensuring that essential reagents and other supplies are available at all times. All reagents are stored and dispensed according to defined procedures. The periodic evaluation of all reagents, such as monitoring expiry dates, ensures accuracy and precise results. Written guidelines ensure the complete and accurate labelling of reagents and solutions.

	Criterion	Comments
		Recommendations
Criterion 9.3.1.1	The available supplies,	
Critical:	consumables, reagents, chemicals and kits are	
Catg: Basic Management + Efficiency	sufficient for projected activities.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.3.1.2	Specific laboratory reagents,	
Critical:	chemicals and kits are used appropriately	
Catg: Basic Management + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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		1
Criterion 9.3.1.3	All reagents and chemicals are stored and dispensed	
Critical:	according to guidelines.	
Catg: Basic Process + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.3.1.4	All reagents and solutions are	
Critical:	completely and accurately labelled.	
Catg: Basic Process + Pat & Staff Safety	labolica.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.3.1.5	All reagents are periodically	
Critical:	evaluated for accuracy of results.	
Catg: Evaluation + Pat & Staff Safety	rocalic.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.3.1.6	All reagents are stored in a	
Critical:	lockable storage room or cupboard.	
Catg: Basic Process + Pat & Staff Safety	ouppourd.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.3.1.7	Where required, reagents are	
Critical:	stored in the correct environment, e.g. controlled	
Catg: Basic Process + Efficiency	temperature, humidity,	
Compliance	exposure to direct sunlight.	
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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Criterion 9.3.1.8	Dangerous reagents and	
Critical:	chemicals are separately and securely stored.	
Catg: Basic Process + Pat & Staff Safety	securely stored.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.3.1.9	All reagents are checked for	
Critical:	expiry dates.	
Catg: Basic Process + Pat & Staff Safety		
Compliance	1	
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.3.1.10	There is a documented stock	
Critical:	management system that	
Catg: Basic Process + Pat & Staff Safety	keeps track of current stock.	
Compliance	1	
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.3.1.11	Re-order levels are defined.	
Critical:	1	
Catg: Basic Process + Efficiency		
Compliance]	
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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9.4 Management of Specimens (Samples) and Results

9.4.1 Standard

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Procedures are followed for collecting, identifying, safely transporting and tracking specimens/samples and reporting the results.

Standard Intent: Procedures are developed and implemented for:

- requesting laboratory tests (laboratory request form)
- specimen collection and identification
- specimen storage, preservation and transport, and
- reviewing and authorising the laboratory results.

There should be at least two log-books: only one patient logbook and at least one logbook for laboratory results. Depending upon the size of the provider and the national requirements of the Ministry of Health, different logbooks for various disciplines are required or mandatory. Logbooks for laboratory results should not be directly linked to names. Patient logbooks should contain name, date of visit, date of birth, gender, which services are requested, what material should be collected and the unique laboratory identification number. In the laboratory logbooks only the unique laboratory number and results are registered. In other words, both logbooks are required to match results to patient names.

Ideally, monthly overviews of the number of tests performed are generated.

Procedures should be available for administration, collection and reporting activities of specimens tested on site or sent to outside referral laboratories.

	Criterion	Comments
		Recommendations
Criterion 9.4.1.1	Policies and procedures	
Critical:	(SOPs) for handling specimens are implemented.	
Catg: Basic Process + Pat & Staff Safety	appearment are implemented.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.4.1.2	Request forms are available	
Critical:	and contain relevant information.	
Catg: Basic Process + Legality		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 9.4.1.3	Specimen labels include	
Critical:	unique patient identification and adequate supporting information.	
Catg: Basic Process + Patient Care		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.4.1.4	Specimens are registered	
Critical:	(handwritten or digital) legibly and in an organised manner.	
Catg: Basic Process + Patient Care	and in an organisca manner.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.4.1.5	Results are registered in a	
Critical:	log-book.	
Catg: Basic Process + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.4.1.6	Laboratory results are stored	
Critical:	in a lockable cupboard.	
Catg: Basic Process + Legality		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.4.1.7	Policies and procedures	
Critical:	(SOPs) regarding reporting and reviewing results are	
Catg: Basic Process + Efficiency	implemented.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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9.4.2 Standard

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Established norms and ranges are used to interpret and report clinical laboratory results.

Standard Intent: The laboratory establishes reference intervals or "normal" ranges for each test performed. The range is included in the clinical record, either as part of the report or by including a current listing of such values, approved by the laboratory director. Ranges are furnished when an outside source performs the test. The reference ranges are appropriate to the organisation's patient population and are reviewed and updated when methods change.

	Criterion	Comments
		Recommendations
Criterion 9.4.2.1	The laboratory has	
Critical:	established reference ranges for relevant tests.	
Catg: Basic Process + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.4.2.2	The range is included in the	
Critical:	clinical record at the time test results are reported.	
Catg: Basic Process + Efficiency	recame and repensed	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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9.5 Quality Control

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9.5.1 Standard

Quality control procedures are followed and documented.

Standard Intent: The quality of the laboratory services can be monitored using internal and external quality control guidelines. Designing and implementing internal and external quality control activities is essential for the final quality assurance of the laboratory results.

Sound quality control systems are essential to providing excellent pathology and clinical laboratory services. Quality control procedures could include:

- validation of the test methods used for accuracy, precision and reportable range
- daily surveillance of results by qualified laboratory personnel rapid corrective action when a deficiency is identified b)
- c)
- d) testing of reagents, and
- documentation of results and corrective actions.

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognised by internal mechanisms. Thus, the laboratory participates in an approved proficiency testing programme when one is available. Alternatively, when approved programmes are not available the laboratory exchanges samples with a laboratory in another organisation for peer comparison testing purposes. The laboratory maintains a cumulative record of participation in a proficiency testing process. Proficiency testing, or an alternative, is carried out for all speciality laboratory programmes, when available.

	Criterion	Comments
		Recommendations
Criterion 9.5.1.1	There is a documented	
Critical:	quality control system.	
Catg: Evaluation + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.5.1.2	The laboratory participates in	
Critical:	an external quality control programme.	
Catg: Evaluation + Efficiency		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.5.1.3	There is a current register of	
Critical:	quality control results and of the corrective and preventive	
Catg: Evaluation + Efficiency	actions taken.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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9.6 Prevention and Control of Infection

9.6.1 Standard

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The laboratory service implements infection prevention and control processes.

	Criterion	Comments
		Recommendations
Criterion 9.6.1.1	The service identifies the	
Critical:	procedures and processes associated with the risk of	
Catg: Basic Management + Efficiency	infection and implements strategies to reduce risk.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.6.1.2	Suitable processes are	
Critical:	followed for cleaning and decontaminating laboratory	
Catg: Basic Process + Pat & Staff Safety	surfaces and equipment.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.6.1.3	Protective clothing is worn	
Critical:	correctly.	
Catg: Basic Process + Pat & Staff Safety		
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		
Criterion 9.6.1.4	Individuals who handle	
Critical:	specimens are trained in the proper handling of dangerous	
Catg: Basic Management + Pat & Staff Safety	specimens.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		

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Criterion 9.6.1.5	Organisational policy on post- exposure prophylaxis (PEP)	
Catg: Basic Process + Pat & Staff Safety	is implemented.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 3 Serious		
Criterion 9.6.1.6	Organisational policy on	
Critical:	handling, storing and disposing of healthcare waste	
Catg: Basic Process + Pat & Staff Safety	is implemented.	
Compliance		
NA NC PC C		
Default Severity for NC or PC = 4 Very Serious		

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