

Qualification Pack



Production Technician: In-vitro Diagnostic (IVD) Kits (Class A and Class B)

QP Code: LFS/Q6201

Version: 1.0

NSQF Level: 4.5

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LFS/Q6201: Production Technician: In-vitro Diagnostic (IVD) Kits (Class A and Class B)

Brief Job Description

The Production Technician for In-Vitro Diagnostic Kits (Class A and Class B) manufacturing is responsible for operating the machines following Good Manufacturing Practices for the manufacturing of In-Vitro Diagnostic Kits (Class A and Class B). The jobholder verifies the output to ensure that in batch manufacturing, the quality parameters are met and performs basic in-process quality checks to ensure total quality management. He/she do routine analysis of manufacturing procedure. He/She also generates the critical records for every activity performed in compliance with data integrity rules. He/she also analyzes and reports production issues to seniors to solve work related problems. He/she also inspects products to verify conformance to specification.

Personal Attributes

The individual should have good communication skills in the regional language and able to comprehend the instructions and process documents in the English language. He/she should have good analytical skills. The job holder should be able to give attention to detail and understand the criticality of work.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N0130: Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area](#)
2. [LFS/N0131: Ensure a hygienic and clean work area to avoid contamination in manufacturing facility](#)
3. [LFS/N6201: Perform pre-production checks and prepare machines for manufacturing operations](#)
4. [LFS/N6202: Perform In-Vitro Diagnostic Kit \(Class A and Class B\) manufacturing operations](#)
5. [LFS/N0133: Coordinate and communicate with supervisor/ engineer, teams and auditors](#)
6. [DGT/VSQ/N0102: Employability Skills \(60 Hours\)](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)



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Occupation	Manufacturing - Medical Devices and IVD
Country	India
NSQF Level	4.5
Credits	15
Aligned to NCO/ISCO/ISIC Code	NCO-2015- 3139.1400
Minimum Educational Qualification & Experience	<p>Pursuing 1st year of UG (in relevant field and Continuous education)</p> <p>OR</p> <p>Pursuing 3rd year of 3-year diploma after 10th (approved by AICTE or State Technical Education Regulatory Body in relevant field and continuous education)</p> <p>OR</p> <p>Pursuing 2nd year of 2-year diploma after 12th (approved by AICTE or State Technical Education Regulatory Body in relevant field and continuous education)</p>
Minimum Level of Education for Training in School	10th Class
Pre-Requisite License or Training	NA
Minimum Job Entry Age	19 Years
Last Reviewed On	NA
Next Review Date	01/11/2026
NSQC Approval Date	01/11/2023
Version	1.0
Reference code on NQR	QG-4.5-LS-01268-2023-V1-LSSSDC
NQR Version	1.0



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LFS/N0130: Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area

Description

This NOS is about ensuring adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area

Scope

The scope covers the following :

- The NOS scope are:
- Follow health and hygiene protocols
- Follow safety and security procedures
- Follow emergency procedures

Elements and Performance Criteria

Follow health and hygiene protocols

To be competent, the user/individual on the job must be able to:

- PC1.** comply with health and personal hygiene-related protocols as per regulatory guidelines/defined ISO class guidelines
- PC2.** ensure cleanroom facilities adhere to strict cleanliness guidelines
- PC3.** wash hands before entering in the production area as per SOP
- PC4.** report any allergy, sickness, or any other environment-related breach before or after entering the work premises to the designated person
- PC5.** ensure wearing cleanroom specialized garments while entering an environment-controlled work area
- PC6.** ensure proper disposal of used accessories

Follow safety and security procedures

To be competent, the user/individual on the job must be able to:

- PC7.** comply with safety and security policies and procedures
- PC8.** use appropriate safety gears like gowns, shoecover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process
- PC9.** use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools
- PC10.** report any identified breaches in safety and security policies and procedures to the designated person
- PC11.** segregate material and follow the 5S system at the storage area
- PC12.** adhere to storage and handling guidelines for hazardous material and volatile chemicals
- PC13.** identify and correct any hazards that one can deal with safely, competently and within the limits of authority
- PC14.** ensure proper disposal of biohazardous material and chemical waste

Follow emergency procedures



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To be competent, the user/individual on the job must be able to:

- PC15.** raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected
- PC16.** inform the concerned person immediately about every unsafe act/ incident
- PC17.** follow emergency protocols efficiently

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** individual's role and responsibilities in maintaining healthy, hygienic, safe and secure working environment
- KU2.** company's procedures and protocols for the environment, health and safety
- KU3.** relevant legislative requirements as per local laws
- KU4.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU5.** workplace hazards in the manufacturing/ research facility in the life sciences sector and reporting procedures for unhealthy/ unsafe act/incidents, hazards and accident as per defined ISO class
- KU6.** limits of individual responsibility for dealing with hazards
- KU7.** chemical substances, their characteristics, and required precaution and safety measures
- KU8.** cleanroom specialized garment
- KU9.** the organization's emergency procedures for different emergency situations and the importance of following these procedures
- KU10.** evacuation procedures for employees, contract staff and visitors
- KU11.** procedure to summon medical assistance and the emergency services, where necessary
- KU12.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU13.** Indian Medical device Rules 2017 and ISO 13485 guidelines for personal hygiene
- KU14.** types of safety gears and procedure to use them
- KU15.** importance of material segregation and 5S system
- KU16.**
 - importance of material segregation and 5S system
 - guidelines for handling and storing hazardous material

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to read instructions, guidelines, procedures, rules, and signages
- GS2.** use written communication skills to accurately record every information required to be reported as per SOP and defined ISO class guidelines in the language prescribed by the company's SOP



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- GS3.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS4.** use critical thinking skills to ascertain the breach/ compliance of EHS protocols
- GS5.** apply customer centricity to remain compliant with data integrity rules, defined ISO class guidelines and to evaluate impact of wrongdoings
- GS6.** apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Follow health and hygiene protocols</i>	15	15	5	5
PC1. comply with health and personal hygiene-related protocols as per regulatory guidelines/defined ISO class guidelines	-	-	-	-
PC2. ensure cleanroom facilities adhere to strict cleanliness guidelines	-	-	-	-
PC3. wash hands before entering in the production area as per SOP	-	-	-	-
PC4. report any allergy, sickness, or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC5. ensure wearing cleanroom specialized garments while entering an environment-controlled work area	-	-	-	-
PC6. ensure proper disposal of used accessories	-	-	-	-
<i>Follow safety and security procedures</i>	15	15	3	3
PC7. comply with safety and security policies and procedures	-	-	-	-
PC8. use appropriate safety gears like gowns, shoe cover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process	-	-	-	-
PC9. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
PC10. report any identified breaches in safety and security policies and procedures to the designated person	-	-	-	-
PC11. segregate material and follow the 5S system at the storage area	-	-	-	-
PC12. adhere to storage and handling guidelines for hazardous material and volatile chemicals	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. identify and correct any hazards that one can deal with safely, competently and within the limits of authority	-	-	-	-
PC14. ensure proper disposal of biohazardous material and chemical waste	-	-	-	-
<i>Follow emergency procedures</i>	10	10	2	2
PC15. raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected	-	-	-	-
PC16. inform the concerned person immediately about every unsafe act/ incident	-	-	-	-
PC17. follow emergency protocols efficiently	-	-	-	-
NOS Total	40	40	10	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0130
NOS Name	Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Generic
NSQF Level	4.5
Credits	1.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023



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LFS/N0131: Ensure a hygienic and clean work area to avoid contamination in manufacturing facility

Description

This NOS is about ensuring a hygienic and clean work area to avoid contamination

Scope

The scope covers the following :

- The NOS scope are:
- Sanitation activities before the start of work
- Sanitation activities during work
- Sanitation activities after completion of work

Elements and Performance Criteria

Sanitation activities before the start of work

To be competent, the user/individual on the job must be able to:

- PC1.** ensure sanitation of cleanroom area as per SOP
- PC2.** check for validation tag on machines and equipments
- PC3.** ensure proper cleaning of machinery and equipments
- PC4.** ensure cleaning validation in the presence of authorized personnel or QA inspector
- PC5.** ensure adequate ventilation during work being carried out
- PC6.** ensure regular sterilization of machinery and equipment
- PC7.** handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method
- PC8.** segregate and store the material with an appropriate label in designated places to avoid contamination

Sanitation activities during work

To be competent, the user/individual on the job must be able to:

- PC9.** segregate and store the intermediate material with an appropriate label in designated places to avoid contamination
- PC10.** report any additional cleaning requirement that is outside one's purview, to the appropriate person
- PC11.** segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel

Sanitation activities after completion of work

To be competent, the user/individual on the job must be able to:

- PC12.** ensure proper disposal of hazardous material and chemical waste
- PC13.** ensure removal of scrap material from work area
- PC14.** ensure cleaning of the equipment after every batch production as per SOP



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- PC15.** perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector
- PC16.** ensure clean and dry area after completion of work as per ISO requirement of sanitized premises

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** levels of hygiene required by production area and the importance of maintaining the same
- KU2.** methodology for production area inspection with methods and materials required for cleaning a variety of surfaces and equipment
- KU3.** methodology to check machinery and equipment on completion of cleaning
- KU4.** procedures for reporting any unidentified soiling or any deviation for cleaning validation
- KU5.** role of different materials, machinery and equipment in cleaning and sanitation of manufacturing area
- KU6.** defined ISO class guidelines for cleaning/ sanitation activity and maintaining hygiene
- KU7.** cleaning validation process

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use written communication skills to record and communicate details of work done to appropriate people using written/typed report and electronic mail
- GS2.** use verbal communication skills to communicate with supervisor, cross-functional teams and auditors effectively
- GS3.** use critical thinking skills to interpret the various coding systems as per company norms and in identifying the non-compliance while performing the area inspection
- GS4.** apply customer centricity at work
- GS5.** apply problem-solving and decision making while dealing with any deviation

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Sanitation activities before the start of work</i>	15	15	5	5
PC1. ensure sanitation of cleanroom area as per SOP	-	-	-	-
PC2. check for validation tag on machines and equipments	-	-	-	-
PC3. ensure proper cleaning of machinery and equipments	-	-	-	-
PC4. ensure cleaning validation in the presence of authorized personnel or QA inspector	-	-	-	-
PC5. ensure adequate ventilation during work being carried out	-	-	-	-
PC6. ensure regular sterilization of machinery and equipment	-	-	-	-
PC7. handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method	-	-	-	-
PC8. segregate and store the material with an appropriate label in designated places to avoid contamination	-	-	-	-
<i>Sanitation activities during work</i>	15	15	3	3
PC9. segregate and store the intermediate material with an appropriate label in designated places to avoid contamination	-	-	-	-
PC10. report any additional cleaning requirement that is outside one's purview, to the appropriate person	-	-	-	-
PC11. segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel	-	-	-	-
<i>Sanitation activities after completion of work</i>	10	10	2	2



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. ensure proper disposal of hazardous material and chemical waste	-	-	-	-
PC13. ensure removal of scrap material from work area	-	-	-	-
PC14. ensure cleaning of the equipment after every batch production as per SOP	-	-	-	-
PC15. perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector	-	-	-	-
PC16. ensure clean and dry area after completion of work as per ISO requirement of sanitized premises	-	-	-	-
NOS Total	40	40	10	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0131
NOS Name	Ensure a hygienic and clean work area to avoid contamination in manufacturing facility
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Generic
NSQF Level	4.5
Credits	1.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023



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LFS/N6201: Perform pre-production checks and prepare machines for manufacturing operations

Description

This NOS is about performing pre-production checks and preparing machines for manufacturing operations

Scope

The scope covers the following :

- The NOS Scope are :
- Material Check
- Pre-production Safety Check
- Prepare machines for manufacturing operations

Elements and Performance Criteria

Material Check

To be competent, the user/individual on the job must be able to:

- PC1.** Ensure stocks of required raw materials are ready and available as per minimum stock required
- PC2.** Perform thorough inspection and verification of quality of all raw material used including reagents, antibodies, antigens and substrate etc.
- PC3.** Ensure availability of crude chemicals and reagents as per SOP
- PC4.** Ensure that critical starting material, raw material, excipients are from a respective batch and analyzed by QC and approved by QA
- PC5.** Match the Batch Code/ Item Code and Authorized Return (AR) No. of each compound/material with the Batch Code ensuring FIFO (First in First Out)
- PC6.** Reach out to the supervisor for rejection control if disparities exist during visual inspection measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size and weight)
- PC7.** Return the unused material to warehouse with the appropriate label

Pre-production Safety check

To be competent, the user/individual on the job must be able to:

- PC8.** Follow safe working instructions as per SOP/ Batch Record and MSDS chemical handling guidelines
- PC9.** Ensure manufacturing process follows relevant safety regulations
- PC10.** Ensure comprehensive risk assessments to identify potential risks
- PC11.** Perform machinery and equipment basic function testing to ensure their proper working
- PC12.** Perform Job Safety Analysis in accordance with International/ National Standards
- PC13.** Secure permit/ authorization to work from appropriate authority

Prepare machines for manufacturing operations

To be competent, the user/individual on the job must be able to:



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- PC14.** Prepare machinery setup and configuration
- PC15.** Ensure that all equipments/ machines are calibrated & validated
- PC16.** Ensure that facilities & equipment are qualified by QA post cleaning validation and equipment validation
- PC17.** Ensure proper loading of material into machine
- PC18.** Perform trial run and random tests to ensure accuracy
- PC19.** Perform routine maintenance of machinery and equipment

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Organizational SOPs relevant to pre-production safety check and preparation of machines for manufacturing operations
- KU2.** Purpose of in-process checks and their procedures
- KU3.** SOP for change request and maintenance of machine
- KU4.** Relevant Data Integrity Rule and Regulatory Guidelines
- KU5.** Equipments used for broad level checks and their operative procedures
- KU6.** Common issues in machine operations and their solutions
- KU7.** Procedure for changeover cleaning
- KU8.** Machinery and equipment calibration process
- KU9.** Process for generating electronic records
- KU10.** Methods for random tests in In-Vitro Diagnostic kits (class A and class B) manufacturing
- KU11.** Critical parameters for specific production machines

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** Record and communicate details of work done to appropriate people using written report or computer based record/electronic mail
- GS2.** Understand the various coding systems as per company norms
- GS3.** Communicate with cross functional team and supervisor
- GS4.** Disclose information only to those who have the right and need to know it
- GS5.** Suggest improvements(if any) in process based on experience
- GS6.** Make decisions related to corrective maintenance and troubleshooting
- GS7.** Analyse the readings of various operational variables and make informed decisions as per SOP
- GS8.** Analyse any situation which needs an immediate escalation or emergency alarm

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Material Check</i>	10	10	2	2
PC1. Ensure stocks of required raw materials are ready and available as per minimum stock required	-	-	-	-
PC2. Perform thorough inspection and verification of quality of all raw material used including reagents, antibodies, antigens and substrate etc.	-	-	-	-
PC3. Ensure availability of crude chemicals and reagents as per SOP	-	-	-	-
PC4. Ensure that critical starting material, raw material, excipients are from a respective batch and analyzed by QC and approved by QA	-	-	-	-
PC5. Match the Batch Code/ Item Code and Authorized Return (AR) No. of each compound/material with the Batch Code ensuring FIFO (First in First Out)	-	-	-	-
PC6. Reach out to the supervisor for rejection control if disparities exist during visual inspection measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size and weight)	-	-	-	-
PC7. Return the unused material to warehouse with the appropriate label	-	-	-	-
<i>Pre-production Safety check</i>	15	15	3	3
PC8. Follow safe working instructions as per SOP/ Batch Record and MSDS chemical handling guidelines	-	-	-	-
PC9. Ensure manufacturing process follows relevant safety regulations	-	-	-	-
PC10. Ensure comprehensive risk assessments to identify potential risks	-	-	-	-
PC11. Perform machinery and equipment basic function testing to ensure their proper working	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. Perform Job Safety Analysis in accordance with International/ National Standards	-	-	-	-
PC13. Secure permit/ authorization to work from appropriate authority	-	-	-	-
<i>Prepare machines for manufacturing operations</i>	15	15	5	5
PC14. Prepare machinery setup and configuration	-	-	-	-
PC15. Ensure that all equipments/ machines are calibrated & validated	-	-	-	-
PC16. Ensure that facilities & equipment are qualified by QA post cleaning validation and equipment validation	-	-	-	-
PC17. Ensure proper loading of material into machine	-	-	-	-
PC18. Perform trial run and random tests to ensure accuracy	-	-	-	-
PC19. Perform routine maintenance of machinery and equipment	-	-	-	-
NOS Total	40	40	10	10



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6201
NOS Name	Perform pre-production checks and prepare machines for manufacturing operations
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Manufacturing - Medical Devices and IVD
NSQF Level	4.5
Credits	3.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023



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LFS/N6202: Perform In-Vitro Diagnostic Kit (Class A and Class B) manufacturing operations

Description

This NOS is about performing In-Vitro Diagnostic Kit (Class A and Class B) manufacturing operations

Scope

The scope covers the following :

- The scope of NOS are
- Manufacturing operations
- In-process check
- Reporting and escalation of deviations

Elements and Performance Criteria

Manufacturing operations

To be competent, the user/individual on the job must be able to:

- PC1.** start batch production activity after collecting Batch Initiation Slip as per SOP
- PC2.** ensure following specifications and steps of master formula to secure product consistency, quality, compliance and reliability
- PC3.** perform cutting of sheets from a roll to specific size and assembling of sheet cutouts into cassette
- PC4.** perform handpressing and machine pressing of the cassettes
- PC5.** perform troubleshooting of machinery and equipments

In-process checks

To be competent, the user/individual on the job must be able to:

- PC6.** ensure no mixing of batches of materials and products
- PC7.** ensure total range of in-process checks specified to be performed after every process as per SOP
- PC8.** use appropriate measuring equipments, tools, accessories etc. as required for carrying out in-process checks
- PC9.** confirm that the intermediate / final product meet the specifications

Reporting and escalation of deviations

To be competent, the user/individual on the job must be able to:

- PC10.** identify non-conformities to quality assurance standards and product specifications
- PC11.** identify potential causes of non-conformities to quality assurance standards with the help of supervisor
- PC12.** implement the corrective and preventive actions as guided by the engineer and quality assurance team

Documentation

To be competent, the user/individual on the job must be able to:



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- PC13.** maintain history records and breakdown maintenance records
- PC14.** maintain electronic documentation for trial runs and random test along with justifications for any wrong entries as applicable
- PC15.** record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and regulatory guidelines
- PC16.** maintain both electronic and manual records in the log books and other documentation required as per regulatory guidelines
- PC17.** update the equipment log books, status boards & ensure in line with the process

Post Production Activities

To be competent, the user/individual on the job must be able to:

- PC18.** perform sealing of kits to avoid cross contamination
- PC19.** carry out segregation of material/ intermediate / finished goods and rejected goods as per SOPs
- PC20.** perform segregation and disposal of waste inline to SOP and as per Environment Sustainable Guidelines and local regulations
- PC21.** provide support for line clearance before the next batch is produced to maintain product consistency, efficiency and quality
- PC22.** follow regular maintenance schedule to extend service life of machinery and equipment

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** clean room behaviour practices and gowning procedures
- KU2.** SOP for entry and exit from manufacturing area
- KU3.** PPE used in IVD kit manufacturing and their work instructions
- KU4.** material, segregation, handling and storage guidelines
- KU5.** type of machinery and equipment used for IVD Kit manufacturing, their operating process and critical parameters
- KU6.** care and maintenance of equipment and machinery
- KU7.** removing and replacing components or parts of machinery and equipment
- KU8.** specialized techniques for IVD kit manufacturing
- KU9.** utilities used in IVD Kit manufacturing
- KU10.** in-process checks for IVD kits manufacturing
- KU11.** printing and labelling guidelines as per regulatory guidelines
- KU12.** procedures of documentation, reporting and escalation of incidents and deviations
- KU13.** procedure of generating electronic records
- KU14.** basic knowledge of ALCOA Principles, Data Integrity and information security rules
- KU15.** procedure of issuance of Crude Chemical
- KU16.** procedure of reagent formulation
- KU17.** procedure of assay dilutions
- KU18.** procedure of cutting sheet roles and assembling them into cassettes



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KU19. procedure of hand pressing and machine pressing the cassettes

KU20. procedure of sealing of IVD kits prepared

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- GS3.** use verbal communication skills in communicating the details of work done to appropriate people and during interaction with regulatory inspectors and other teammates
- GS4.** use planning and organizing skills in every activity planned and performed in IVD Kit manufacturing operations and to achieve resource optimization
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS7.** use critical skills in analyzing impact of deviations, wastage and rejects to the environment and efficiency, compliance and cost
- GS8.** demonstrate decision making while making necessary adjustments in parameters to achieve quality specifications
- GS9.** apply customer-centricity while responding to auditors and QA personnel

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Manufacturing operations</i>	10	10	2	2
PC1. start batch production activity after collecting Batch Initiation Slip as per SOP	-	-	-	-
PC2. ensure following specifications and steps of master formula to secure product consistency, quality, compliance and reliability	-	-	-	-
PC3. perform cutting of sheets from a roll to specific size and assembling of sheet cutouts into cassette	-	-	-	-
PC4. perform handpressing and machine pressing of the cassettes	-	-	-	-
PC5. perform troubleshooting of machinery and equipments	-	-	-	-
<i>In-process checks</i>	10	10	2	2
PC6. ensure no mixing of batches of materials and products	-	-	-	-
PC7. ensure total range of in-process checks specified to be performed after every process as per SOP	-	-	-	-
PC8. use appropriate measuring equipments, tools, accessories etc. as required for carrying out in-process checks	-	-	-	-
PC9. confirm that the intermediate / final product meet the specifications	-	-	-	-
<i>Reporting and escalation of deviations</i>	5	5	2	2
PC10. identify non-conformities to quality assurance standards and product specifications	-	-	-	-
PC11. identify potential causes of non-conformities to quality assurance standards with the help of supervisor	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. implement the corrective and preventive actions as guided by the engineer and quality assurance team	-	-	-	-
<i>Documentation</i>	5	5	2	2
PC13. maintain history records and breakdown maintenance records	-	-	-	-
PC14. maintain electronic documentation for trial runs and random test along with justifications for any wrong entries as applicable	-	-	-	-
PC15. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and regulatory guidelines	-	-	-	-
PC16. maintain both electronic and manual records in the log books and other documentation required as per regulatory guidelines	-	-	-	-
PC17. update the equipment log books, status boards & ensure in line with the process	-	-	-	-
<i>Post Production Activities</i>	10	10	2	2
PC18. perform sealing of kits to avoid cross contamination	-	-	-	-
PC19. carry out segregation of material/ intermediate / finished goods and rejected goods as per SOPs	-	-	-	-
PC20. perform segregation and disposal of waste inline to SOP and as per Environment Sustainable Guidelines and local regulations	-	-	-	-
PC21. provide support for line clearance before the next batch is produced to maintain product consistency, efficiency and quality	-	-	-	-
PC22. follow regular maintenance schedule to extend service life of machinery and equipment	-	-	-	-
NOS Total	40	40	10	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6202
NOS Name	Perform In-Vitro Diagnostic Kit (Class A and Class B) manufacturing operations
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Manufacturing - Medical Devices and IVD
NSQF Level	4.5
Credits	6.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023



Qualification Pack

LFS/N0133: Coordinate and communicate with supervisor/ engineer, teams and auditors

Description

This NOS unit is about coordinating and communicating with supervisor/ engineer, teams and auditors

Scope

The scope covers the following :

- Coordination with supervisor/engineer
- Team coordination
- Respond to audit queries
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with supervisor/engineer

To be competent, the user/individual on the job must be able to:

- PC1.** follow work instructions received from the reporting supervisor
- PC2.** adhere to the production plan to meet timelines
- PC3.** communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor
- PC4.** ensure timely intimation to supervisor/ production engineer about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention
- PC5.** engage with supervisor on work-related and behavioral feedback and demonstrate continual learning and self-direction

Team coordination

To be competent, the user/individual on the job must be able to:

- PC6.** support team members and colleagues of other departments in work
- PC7.** take handover from previous shift operator and give handover to next shift operator as per SOP
- PC8.** guide manufacturing and packaging assistants during manufacturing process
- PC9.** coordinate with warehouse team for material dispensing and issuance
- PC10.** find solutions for workflow related difficulties with mutual agreement
- PC11.** coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors
- PC12.** coordinate with quality control team for sample collection, batch release and in-process checks
- PC13.** coordinate with quality assurance team for machine/ equipment validation at a routine interval as per SOP
- PC14.** provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance



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PC15. coordinate with EHS team for any safety incident, accident and emergency

Respond to audit queries

To be competent, the user/individual on the job must be able to:

PC16. ensure interact with auditor in a preferable language

PC17. provide an honest and clear answer to the raised queries

PC18. maintain data integrity while responding to auditors or while producing the documented records for activities performed

Sensitivity towards all genders and people with disability

To be competent, the user/individual on the job must be able to:

PC19. respect all genders, religions, and caste

PC20. empathize with the people with disability

PC21. offer support or help to a person with disability only when asked

PC22. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC23. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the company's policies on the preferred language of communication, reporting and escalation policy

KU2. the reporting structure of the organization

KU3. types of audits in the life sciences sector for the manufacturing operations

KU4. the required regulatory and statutory compliance-related documentation

KU5. the guidelines for data integrity, ethics, and compliance in the life sciences industry

KU6. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU7. the methods of workplace communication

KU8. importance of team coordination

KU9. the types of possible disabilities among people with disability (PwD)

KU10. the challenges faced by PwD

KU11. the importance of displaying empathy towards PwD

KU12. the right way to use the laws, acts, and provisions defined for PwD by the statutory bodies

KU13. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU14. importance of respecting all gender identities, religion, caste, and culture

KU15. method to receive the performance feedback

Generic Skills (GS)

User/individual on the job needs to know how to:



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- GS1.** use reading and comprehension skills to gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/ comments
- GS2.** use written communication skills to record and communicate details of work done to appropriate stakeholders by using written or computer-based record/ electronic mail in a given format and compliant with ALCOA principle
- GS3.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates
- GS4.** use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS7.** apply customer-centricity skills while responding to auditors and QA personnel

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with supervisor/engineer</i>	10	10	4	4
PC1. follow work instructions received from the reporting supervisor	-	-	-	-
PC2. adhere to the production plan to meet timelines	-	-	-	-
PC3. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor	-	-	-	-
PC4. ensure timely intimation to supervisor/ production engineer about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention	-	-	-	-
PC5. engage with supervisor on work-related and behavioral feedback and demonstrate continual learning and self-direction	-	-	-	-
<i>Team coordination</i>	10	10	2	2
PC6. support team members and colleagues of other departments in work	-	-	-	-
PC7. take handover from previous shift operator and give handover to next shift operator as per SOP	-	-	-	-
PC8. guide manufacturing and packaging assistants during manufacturing process	-	-	-	-
PC9. coordinate with warehouse team for material dispensing and issuance	-	-	-	-
PC10. find solutions for workflow related difficulties with mutual agreement	-	-	-	-
PC11. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. coordinate with quality control team for sample collection, batch release and in-process checks	-	-	-	-
PC13. coordinate with quality assurance team for machine/ equipment validation at a routine interval as per SOP	-	-	-	-
PC14. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance	-	-	-	-
PC15. coordinate with EHS team for any safety incident, accident and emergency	-	-	-	-
<i>Respond to audit queries</i>	10	10	2	2
PC16. ensure interact with auditor in a preferable language	-	-	-	-
PC17. provide an honest and clear answer to the raised queries	-	-	-	-
PC18. maintain data integrity while responding to auditors or while producing the documented records for activities performed	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	10	10	2	2
PC19. respect all genders, religions, and caste	-	-	-	-
PC20. empathize with the people with disability	-	-	-	-
PC21. offer support or help to a person with disability only when asked	-	-	-	-
PC22. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace(Prevention, Prohibition and Redressal) Act	-	-	-	-
PC23. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	40	40	10	10



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0133
NOS Name	Coordinate and communicate with supervisor/ engineer, teams and auditors
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Generic
NSQF Level	4.5
Credits	1
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023



Qualification Pack

DGT/VSQ/N0102: Employability Skills (60 Hours)

Description

This unit is about employability skills, Constitutional values, becoming a professional in the 21st Century, digital, financial, and legal literacy, diversity and Inclusion, English and communication skills, customer service, entrepreneurship, and apprenticeship, getting ready for jobs and career development.

Scope

The scope covers the following :

- Introduction to Employability Skills
- Constitutional values - Citizenship
- Becoming a Professional in the 21st Century
- Basic English Skills
- Career Development & Goal Setting
- Communication Skills
- Diversity & Inclusion
- Financial and Legal Literacy
- Essential Digital Skills
- Entrepreneurship
- Customer Service
- Getting ready for Apprenticeship & Jobs

Elements and Performance Criteria

Introduction to Employability Skills

To be competent, the user/individual on the job must be able to:

- PC1.** identify employability skills required for jobs in various industries
- PC2.** identify and explore learning and employability portals

Constitutional values – Citizenship

To be competent, the user/individual on the job must be able to:

- PC3.** recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.
- PC4.** follow environmentally sustainable practices

Becoming a Professional in the 21st Century

To be competent, the user/individual on the job must be able to:

- PC5.** recognize the significance of 21st Century Skills for employment
- PC6.** practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life

Basic English Skills

To be competent, the user/individual on the job must be able to:



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- PC7.** use basic English for everyday conversation in different contexts, in person and over the telephone
- PC8.** read and understand routine information, notes, instructions, mails, letters etc. written in English
- PC9.** write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

To be competent, the user/individual on the job must be able to:

- PC10.** understand the difference between job and career
- PC11.** prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

To be competent, the user/individual on the job must be able to:

- PC12.** follow verbal and non-verbal communication etiquette and active listening techniques in various settings
- PC13.** work collaboratively with others in a team

Diversity & Inclusion

To be competent, the user/individual on the job must be able to:

- PC14.** communicate and behave appropriately with all genders and PwD
- PC15.** escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

To be competent, the user/individual on the job must be able to:

- PC16.** select financial institutions, products and services as per requirement
- PC17.** carry out offline and online financial transactions, safely and securely
- PC18.** identify common components of salary and compute income, expenses, taxes, investments etc
- PC19.** identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

To be competent, the user/individual on the job must be able to:

- PC20.** operate digital devices and carry out basic internet operations securely and safely
- PC21.** use e- mail and social media platforms and virtual collaboration tools to work effectively
- PC22.** use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

To be competent, the user/individual on the job must be able to:

- PC23.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- PC24.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- PC25.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

To be competent, the user/individual on the job must be able to:

- PC26.** identify different types of customers
- PC27.** identify and respond to customer requests and needs in a professional manner.



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PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

To be competent, the user/individual on the job must be able to:

PC29. create a professional Curriculum vitae (Résumé)

PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC31. apply to identified job openings using offline /online methods as per requirement

PC32. answer questions politely, with clarity and confidence, during recruitment and selection

PC33. identify apprenticeship opportunities and register for it as per guidelines and requirements

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. need for employability skills and different learning and employability related portals

KU2. various constitutional and personal values

KU3. different environmentally sustainable practices and their importance

KU4. Twenty first (21st) century skills and their importance

KU5. how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up

KU6. importance of career development and setting long- and short-term goals

KU7. about effective communication

KU8. POSH Act

KU9. Gender sensitivity and inclusivity

KU10. different types of financial institutes, products, and services

KU11. how to compute income and expenditure

KU12. importance of maintaining safety and security in offline and online financial transactions

KU13. different legal rights and laws

KU14. different types of digital devices and the procedure to operate them safely and securely

KU15. how to create and operate an e- mail account and use applications such as word processors, spreadsheets etc.

KU16. how to identify business opportunities

KU17. types and needs of customers

KU18. how to apply for a job and prepare for an interview

KU19. apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. read and write different types of documents/instructions/correspondence

GS2. communicate effectively using appropriate language in formal and informal settings



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- GS3.** behave politely and appropriately with all
- GS4.** how to work in a virtual mode
- GS5.** perform calculations efficiently
- GS6.** solve problems effectively
- GS7.** pay attention to details
- GS8.** manage time efficiently
- GS9.** maintain hygiene and sanitization to avoid infection

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to Employability Skills</i>	1	1	-	-
PC1. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
<i>Constitutional values – Citizenship</i>	1	1	-	-
PC3. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.	-	-	-	-
PC4. follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	2	4	-	-
PC5. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC6. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life	-	-	-	-
<i>Basic English Skills</i>	2	3	-	-
PC7. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC9. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development & Goal Setting</i>	1	2	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. understand the difference between job and career	-	-	-	-
PC11. prepare a career development plan with short- and long-term goals, based on aptitude	-	-	-	-
<i>Communication Skills</i>	2	2	-	-
PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
PC13. work collaboratively with others in a team	-	-	-	-
<i>Diversity & Inclusion</i>	1	2	-	-
PC14. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC15. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
<i>Financial and Legal Literacy</i>	2	3	-	-
PC16. select financial institutions, products and services as per requirement	-	-	-	-
PC17. carry out offline and online financial transactions, safely and securely	-	-	-	-
PC18. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	3	4	-	-
PC20. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-
PC22. use basic features of word processor, spreadsheets, and presentations	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Entrepreneurship</i>	2	3	-	-
PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	1	2	-	-
PC26. identify different types of customers	-	-	-	-
PC27. identify and respond to customer requests and needs in a professional manner.	-	-	-	-
PC28. follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	2	3	-	-
PC29. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC31. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC32. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC33. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	20	30	-	-



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0102
NOS Name	Employability Skills (60 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	4
Credits	2
Version	1.0
Last Reviewed Date	31/01/2024
Next Review Date	31/01/2027
NSQC Clearance Date	31/01/2024

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)
2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.
3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.
4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.
5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and viva for every student at each examination/training center based on this criterion.
6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied



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assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50%-70% of marks in each NOS (depending on NSQF Level) to successfully clear the assessment. In the case of a Govt funded program, the program guidelines will be overarching on the pass percentage rules.

8. In case of unsuccessful completion, the trainee may seek re-assessment on the Qualification Pack.

Minimum Aggregate Passing % at QP Level : 70

(Please note: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

Minimum Passing % at NOS Level: 70

(Please note: A Trainee must score the minimum percentage for each NOS separately as well as on the QP as a whole.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0130.Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area	40	40	10	10	100	10
LFS/N0131.Ensure a hygienic and clean work area to avoid contamination in manufacturing facility	40	40	10	10	100	10
LFS/N6201.Perform pre-production checks and prepare machines for manufacturing operations	40	40	10	10	100	30
LFS/N6202.Perform In-Vitro Diagnostic Kit (Class A and Class B) manufacturing operations	40	40	10	10	100	30



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0133.Coordinate and communicate with supervisor/ engineer, teams and auditors	40	40	10	10	100	10
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	10
Total	220	230	50	50	550	100



Qualification Pack

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
SOP	Standard Operating procedure
QA	Quality Assurance
QC	Quality Control
MSDS	Material Safety Data Sheet
SOP	Standard Operating Procedure
ISO	International Organization for Standardization
EHS	Environment, Health and Safety
SOP	Standard Operating Procedure
ISO	International Organization for Standardization
EHS	Environment, Health and Safety
QA	Quality Assurance
SOP	Standard Operating procedure
QA	Quality Assurance
QC	Quality Control
MSDS	Material Safety Data Sheet
SOP	Standard Operating Procedure
IVD	In-Vitro Diagnostic
PPE	Personal Protective Equipment
ALCOA	Attributable, Legible, Contemporaneous, Original, and Accurate
QA	Quality Assurance
SOP	Standard Operating Procedure



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ISO	International Organization for Standardization
EHS	Environment, Health and Safety
SOP	Standard Operating Procedure
QA	Quality Assurance
POSH	Prevention of Sexual Harassment
PwD	People With Disability
ALCOA	Attributable, Legible, Contemporaneous, Original and Accurate
EHS	Environment, Health and Safety

Qualification Pack

Glossary

Sector	Sector is a conglomeration of different business operations having similar business and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.
Sub-sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Occupation	Occupation is a set of job roles, which perform similar/ related set of functions in an industry.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Occupational Standards (OS)	OS specify the standards of performance an individual must achieve when carrying out a function in the workplace, together with the Knowledge and Understanding (KU) they need to meet that standard consistently. Occupational Standards are applicable both in the Indian and global contexts.
Performance Criteria (PC)	Performance Criteria (PC) are statements that together specify the standard of performance required when carrying out a task.
National Occupational Standards (NOS)	NOS are occupational standards which apply uniquely in the Indian context.
Qualifications Pack (QP)	QP comprises the set of OS, together with the educational, training and other criteria required to perform a job role. A QP is assigned a unique qualifications pack code.
Unit Code	Unit code is a unique identifier for an Occupational Standard, which is denoted by an 'N'
Unit Title	Unit title gives a clear overall statement about what the incumbent should be able to do.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate OS they are looking for.
Scope	Scope is a set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on quality of performance required.
Knowledge and Understanding (KU)	Knowledge and Understanding (KU) are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.

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Organisational Context	Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Technical Knowledge	Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Core Skills/ Generic Skills (GS)	Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.
Electives	Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.
Options	Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.
National Occupational Standard	NOS define the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
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