CURRICULUM

FOR THE TRADE OF

LABORATORY ASSISTANT – IMMUNO DIAGNOSTICS

(Production/ Manufacturing Plant)

UNDER

APPRENTICESHIP TRAINING SCHEME

GOVERNMENT OF INDIA

MINISTRY OF SKILL DEVELOPMENT AND ENTREPRENEURSHIP

DIRECTORATE GENERAL OF TRAINING

1. Category of trade : Non-Engineering

2. Name of the Trade : Laboratory Assistant – Immuno Diagnostics
(Production/ Manufacturing Plant)

3. Duration of Apprenticeship Training : **15 Months**

Break up of the Apprenticeship Training

(i) Duration of Basic Training : 3 Months / 500 Hrs

(ii) Duration of Practical Training/ On-the-job Training : 12 Months

4. Entry Qualification : Passed 8th Class

(A) <u>Basic training components</u>

(i) Employability Skills - 110 Hrs

(ii) Basic numeracy - Not Applicable

(iii) Trade theory - 120 Hrs

(iv) Trade practical - 270 Hrs

(B) Practical Training/On-the job training : 12 Months

CONTENTS

1. ACKNOWLEDGEMENT

In-Vitro Diagnostic Sector sincerely acknowledges with thanks the contribution and cooperation extended by Shri. P.A. Mistry, Deputy Director of Employment and Training to bring out this curriculum for the trade of **Laboratory Assistant – Immuno Diagnostics**under Apprenticeship Training Scheme.

We also acknowledge the team member of apprentice authority for their timely guidance and support for preparing this course curriculum.

2. BACKGROUND

2. 1. Apprenticeship Training Scheme under Apprentice Act 1961

The Apprentices Act, 1961 was enacted with the objective of regulating the programme of training of apprentices in the industry by utilizing the facilities available therein for imparting on-the-job training. The Act makes it obligatory for employers in specified industries to engage apprentices in designated trades to impart Apprenticeship Training on the job in industry to school leavers and person having National Trade Certificate(ITI pass-outs) issued by National Council for Vocational Training (NCVT) to develop skilled manpower for the industry**.** There are four categories of apprentices namely**; trade apprentice, graduate, technician and technician (vocational) apprentices.**

Qualifications and period of apprenticeship training of **trade apprentices** vary from trade to trade. The apprenticeship training for trade apprentices consists of basic training followed by practical training. At the end of the training, the apprentices are required to appear in a trade test conducted by NCVT and those successful in the trade tests are awarded the National Apprenticeship Certificate.

The period of apprenticeship training for graduate (engineers), technician (diploma holders and technician (vocational) apprentices is one year. Certificates are awarded on completion of training by the Department of Education, Ministry of Human Resource Development.

2. 2. Changes in Industrial Scenario

Recently we have seen huge changes in the Indian industry. The Indian Industry registered an impressive growth during the last decade and half. The number of industries in India have increased manifold in the last fifteen years especially in services and manufacturing sectors. It has been realized that India would become a prosperous and a modern state by raising skill levels, including by engaging a larger proportion of apprentices, will be critical to success; as will stronger collaboration between industry and the trainees to ensure the supply of skilled workforce and drive development through employment. Various initiatives to build up an adequate infrastructure for rapid industrialization and improve the industrial scenario in India have been taken.

2. 3. Reformation

The Apprentices Act, 1961 has been amended and brought into effect from 22nd December, 2014 to make it more responsive to industry and youth. Key amendments are as given below:

- Prescription of number of apprentices to be engaged at establishment level instead of trade-wise.
- Establishment can also engage apprentices in optional trades which are not designated, with the discretion of entry level qualification and syllabus.
- Scope has been extended also to non-engineering occupations.
- Establishments have been permitted to outsource basic training in an institute of their choice.
- The burden of compliance on industry has been reduced significantly.

3. RATIONALE

[Need for Apprenticeship as Laboratory Assistant – Immuno Diagnostics]

The candidate trained in this job role will be employed only in the production section for manufacturing diagnostic products. It provides knowledge of manufacturing procedures carried out at production floor.

The greater degree of relevance of the training with latest advancements of the industry will enhance the employability opportunities.

1. Knowledge of gowning procedure for entry into manufacturing area.
2. Ability to use latest machines and their different techniques related to manufacturing operations.
3. Knowledge of material movement process, washing, filling and sterilization, centrifugation, filtration, ageing, and solution preparation.
4. Acquire knowledge of issuing of raw materials, packaging materials from warehouse and preparation of diagnostic reagents in different production sections. Co-ordination with other departments for filling of reagents for different environmental conditions.
5. Ability to use the computer for electronic documentation of information and understand instructions while batch production.
6. Ability to use the company software to manage and update logs.
7. Exposure to production planning, batch creation and packaging of the final products.
8. Prioritize the queries obtained and plan for the day.
9. Resolve the query within the target turnaround time (TAT).
10. Ability to concentrate on task at hand and complete it without errors.
11. Ability to understand the system information and location information of materials available and maintain accuracy.
12. Identify and resolve the queries in day-to-day manufacturing operations.
13. Exposure to regulations, use of work equipment, maintenance, control of materials hazardous to health with respect to Safety and Security aspects.

14. Ability to understand the additional information required and contact details of the relevant personnel in the department.
15. Ability to manage expectations of other sections of the organisation.
16. Able to communicate and behave in a professional manner when dealing with customers, colleagues and supervisors.
17. Knowledge of Risk and impact of not following defined procedures/work instructions.
18. Able to understand clearly and gaining extensive knowledge of the company, services offered and related solutions to problems.
19. Exposure to Reporting and documentation.
20. Ability to understand and maintain health, safety and security standards during manufacturing process.

4. JOB ROLE

Brief description of Job role:

1. Issuance of material from store.
2. Washing and drying product containers.
3. Assembly preparation for flow through products.
4. Arrangement of flow through device in SS tray.
5. Scanning and drying of spotted device.
6. Primary packing of dried spotted device and assembling device in aluminium pouch.
7. Assembling of test card (sticking of various test components) lamination.
8. Cutting of assembled card into test strip.
9. Assembling of test strip into device.
10. Primary packing of assembling dipsticks in aluminium blister pack.
11. Cutting of HIPS sheet.
12. Spotting and drying process of antigen/antibody on HIPS sheet.
13. Scanning of spotted comb.
14. Fixing, blocking, stabilizing and final drying of spotted comb.
15. Packing of dried comb.
16. Sticking of desiccant card, arrow tape and two way tape on spotted comb.
17. Cutting, scanning and primary packing of single test comb in aluminium blister pack.
18. Centrifugation of comb based, flow through and lateral flow gold.
19. Coating, blocking and stabilizing of antigen/antibody on immuno-sorbent assay plate.
20. Primary packing of immuno-sorbent assay plate into aluminium pouch.

5. LEARNING OUTCOMES

A. GENERIC OUTCOME:

- cGMP methods required in Manufacturing & testing of In Vitro Diagnostics.
- Identification, Traceability and Status labelling in Production, QA, QC under cGMP environment.
- Safety measures while handling Biohazard materials
- Work environment practices such as housekeeping, safety & 5 'S.
- Soft skills such as English communication, team building, effective supervision etc.

B. SPECIFIC OUTCOME

- Production & Quality control techniques for In vitro Diagnostics
- Method of cleanliness of product and Contamination control
- Standard requirements of Document & record control
- To perform in process quality check during manufacturing stages.
- Standard requirements of Storage & Handling of Various type of Raw materials.eg. Biohazard, Solvents etc.
- Concept of Machine / Equipment's operation.
- Stage wise material reconciliation
- Detect and escalate amorality of process

1. GENERAL INFORMATION

1.	Name of the Trade	:	Laboratory Assistant – Immuno Diagnostics (Production / Manufacturing Plant)
2.	Duration of Apprenticeship Training	:	15 Months
	Basic Training	:	3 Months
	Practical Training	:	12 Months
3.	Duration of Basic Training	:	
	a. Block –I	:	3 months
4.	Total duration of Basic Training	:	3 Months
5.	Duration of Practical Training (On -job Training)	:	52 Weeks or 12 Months
6.	Entry Qualification	:	Passed 8thclass
7.	Selection of Apprentices	:	The apprentices will be selected asper Apprenticeship Act amended time to time.
8.	Rebate for ITI passed trainees	:	NA

Note: *Industry may impart training as per above time schedule, however this is not fixed. The industry may adjust the duration of training considering the fact that all the components under the syllabus must be covered. However the flexibility should be given keeping in view that no safety aspect is compromised and duration of industry training to be remains as 1 year.*

7. COURSE STRUCTURE

Training duration details:

Time (in hours)	**500 Hrs (3 Months)**	**12 months**
Basic Training	Block– I	-----
Practical Training (On - job training)	----	Block – II

Components of Training	**Duration of Training in Months** →														
↓	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Basic Training Block – I															
Practical Training Block - II															

8. SYLLABUS

8.1 BASIC TRAINING

(BLOCK – I)

DURATION: 03 MONTHS

GENERAL INFORMATION

1) Name of the Trade : Laboratory Assistant – Immuno Diagnostics

(Production / Manufacturing plant)

2) Hours of Instruction : 500 Hrs.

3) Batch size : 25

4) Power Norms : NA

5) Space Norms : 192 Sq. m.

6) Examination : The internal assessment will be held on completion of each Block.

7) Instructor Qualification :

Degree/Diploma in Pharmacy/Science (Biotechnology, Microbiology, Chemistry) or Master of Science from recognized university/Board with one/two year post qualification experience respectively in the relevant field.

8) Tools, Equipment's & Machinery required: - As per Annexure – I

8.1.1 Details of Syllabus of Core Skill

Duration 500Hrs

Sr. No.	Trade Practical (Professional Skills)	Duration 270Hrs	Trade Theory (Professional Knowledge)	Duration 120Hrs
1	• Site Visit to Manufacturing Plant		• Work function of each departments • Processes of departments • Manufacturing technique and method	
2	• Basic information about Diagnostic Products • Manufacturing and testing of different type of product		• Type of Products • Application of Product • Bio - safety measures for products • Working Principal of products for eg. Elisa, Rapid test technology	
3	• Good documentation practices		• Knowledge of cGMP • Knowledge of Regulatory and compliances.	
4	• Work Environment • SIP(Sterilisation In Place • Cleaning In Place		• Lab Safety • Gowning Procedures • Instrument Handling • Bio Hazard Handling • Prevent cross contamination	
5	• Material Handling process • Batch dispensing process • Handling of Anti-Dot		• Knowledge about material safety datasheet • Application of material • Storage of material • Handling of Hygroscopic material • Handling hazardous material e.g Solvent	
6	• Safety Precaution in production area		• Knowledge of Bio hazards material • Knowledge about material safety datasheet • Knowledge about personal protective equipment's	

7	• Equipment/Instrument Qualification method and process • Type of equipment's		• Knowledge of instrument SOP • Application of Instrument • Type of equipment's and standard	
8	• Waste Disposal • Uses of Disposal Bag • Operation of ETP (Effluent Treatment Plant)		• Type of Waste; • Knowledge about Bio-Safety • Knowledge of hazardous materials • Knowledge of ETP (Effluent Treatment Plant)	
9	• Labelling Practice and Printing • Operation of Label printing machine • Assembling of various type of Kit, Product		• Knowledge about concerned SOP's of labelling • About Label Printing Machine	
10	• Entry and Exit Procedure for Low Bio burden Area and Clean Rooms in Production		• Gowning Process • Knowledge about classification of Bio burden Area	
11	• Operation of Product Container washing machine		• Do's and Don'ts during washing and cleaning • Methodology of washing	
12	• Water treatment Plant operation		• Basic Knowledge of water. • Types of Water(RO, Purified, Ultrapure)	
13	• Basic cGMP compliance		• Knowledge of handling of respective procedures • Applicable regulatory guidelines and departmental SOP's and DP's	
14	• Practical approach of 5S Training.		• Learning of 5S concept • Meaning of 5S • Implementation process of 5S	

15	• Kaizen Implementation at workplace		• Meaning and concept of Kaizen • Effectiveness of Kaizen concept • Category of Kaizen	
16	• Operation of Robotic Dispenser I & J 7900-LF • Dispensing test and Control solution of HIV kit • Attach the test and control solution • Check the spot size		• Function of Robotic Dispenser I & J 7900-LF • Uses and parts of Robotic Dispenser I & J 7900-LF • Theory of checking spot Size	
17	• Setting the parameter of Comb Cutting machine • Making various size of comb • Check the comb size		• Theory on how to set machine parameter • Quality check parameter of comb	
18	• Operation of Isoflow machine • Checking the test and control line distance • Change the tubing		• Theory on how to attach test and control solution • Theory to measure distance between test and control • Quality measure of NCM (Nitro Cellulous Membrane)	
19	• Operation of Vertical Laminar Air Flow • Work station for Classified Area to maintain Practical and bacteria free environment condition		• Classification of Area and Purpose. • About Laminar and its uses	

20	• Ultrapure water System operation.		• Theory of Water System, and How to Pure water • Use of various cartilage for filtration	
21	• Operation of Hot plate cum stirrer (C-MAG HS7) • Mixing of Solution which use in reagent • Setting the temperature		• Theory on operation of Hot plate cum stirrer (C-MAG HS7) • Theory on Temperature and Speed Control	
22	• Operation of Lyophilizer, for G6 PD test (Glucose Six Phosphate Dehydrozination) • How to restart in case of power failure		• What is freeze drying and vacuum drying • Theory of maintaining temperature parameter	
23	• Operation of Bottle and Vial filling machine • Adjusting the desire volume of liquid to dispense and filling. • Cleaning and checking of bottle		• Its Function and How to dispense liquid in bottles and vials • How to suction and deliver in bottle and vial	
24	• Operation of Automatic Aluminium Cap Sealing machine • Sealing the container with aluminium seal • Check leakage and quality of sealing		• Type of Seal, • Function of machine	
25	• Operation of Mechanical stirrer • Mixing of solution used in reagent		• Theory of operation • Speed Control Theory • Bigger volume mixing process	

8.1.2 EMPLOYABILITY SKILLS

GENERAL INFORMATION

1)	**Name of the subject**	**:**	**EMPLOYABILITY SKILLS**
2)	**Applicability**	**:**	ATS- Mandatory for fresher only
3)	**Hours of Instruction**	**:**	110 Hrs.
4)	**Examination**	**:**	The examination will be held at the end of Training by NCVT.
5)	**Instructor Qualification**	**:**	

i) MBA/BBA with two years experience or graduate in sociology/social welfare/Economics with two years experience and trained in Employability skill from DGET Institute.

And

Must have studied in English/Communication Skill and Basic Computer at 12^{th} /diploma level

OR

ii) Existing Social Study Instructor duly trained in Employability Skill from DGET Institute.

8.1.3 SYLLABUS OF EMPLOYABILITY SKILLS

Block – I
Basic Training

Topic No.	Topic	Duration (in hours)
	English Literacy	**20**
1	**Pronunciation :** Accentuation (mode of pronunciation) on simple words, Diction (use of word and speech)	
2	**Functional Grammar** Transformation of sentences, Voice change, Change of tense, Spellings.	
3	**Reading** Reading and understanding simple sentences about self, work and environment	
4	**Writing** Construction of simple sentences Writing simple English	
5	**Speaking / Spoken English** Speaking with preparation on self, on family, on friends/ classmates, on know, picture reading gain confidence through role-playing and discussions on current happening job description, asking about someone's job habitual actions. Cardinal (fundamental) numbers ordinal numbers. Taking messages, passing messages on and filling in message forms Greeting and introductions office hospitality, Resumes or curriculum vita essential parts, letters of application reference to previous communication.	

	I.T. Literacy	
1	**Basics of Computer** Introduction, Computer and its applications, Hardware and peripherals, Switching on-Starting and shutting down of computer.	
2	**Computer Operating System** Basics of Operating System, WINDOWS, The user interface of Windows OS, Create, Copy, Move and delete Files and Folders, Use of External memory like pen drive, CD, DVD etc, Use of Common applications.	
3	**Word processing and Worksheet** Basic operating of Word Processing, Creating, opening and closing Documents, use of shortcuts, Creating and Editing of Text, Formatting the Text, Insertion & creation of Tables. Printing document. Basics of Excel worksheet, understanding basic commands, creating simple worksheets, understanding sample worksheets, use of simple formulas and functions, Printing of simple excel sheets	**20**
4	**Computer Networking and INTERNET** Basic of computer Networks (using real life examples), Definitions of Local Area Network (LAN), Wide Area Network (WAN), Internet, Concept of Internet (Network of Networks), Meaning of World Wide Web (WWW), Web Browser, Web Site, Web page and Search Engines. Accessing the Internet using Web Browser, Downloading and Printing Web Pages, Opening an email account and use of email. Social media sites and its implication. Information Security and antivirus tools, Do's and Don'ts in Information Security, Awareness of IT - ACT, types of cyber crimes.	

	Communication Skill	
1	**Introduction to Communication Skills** Communication and its importance Principles of Effective communication Types of communication - verbal, non verbal, written, email, talking on phone. Non verbal communication -characteristics, components-Para-language Body - language Barriers to communication and dealing with barriers. Handling nervousness/ discomfort.	
2	**Listening Skills** Listening-hearing and listening, effective listening, barriers to effective listening guidelines for effective listening. Triple- A Listening - Attitude, Attention & Adjustment. Active Listening Skills.	**15**
3	**Motivational Training** Characteristics Essential to Achieving Success The Power of Positive Attitude Self awareness Importance of Commitment Ethics and Values Ways to Motivate Oneself Personal Goal setting and Employability Planning.	
4	**Facing Interviews** Manners, Etiquettes, Dress code for an interview Do's & Don'ts for an interview	
5	**Behavioral Skills** Problem Solving Confidence Building Attitude	

Topic No.	Topic	Duration (in hours)
	Entrepreneurship skill	**15**
1	**Concept of Entrepreneurship** **Entrepreneurship** - Entrepreneurship - Enterprises:- Conceptual issue Entrepreneurship vs. Management, Entrepreneurial motivation. Performance & Record, Role & Function of entrepreneurs in relation to the enterprise & relation to the economy, Source of business ideas, Entrepreneurial opportunities, The process of setting up a business.	
2	**Project Preparation & Marketing analysis** Qualities of a good Entrepreneur, SWOT and Risk Analysis. Concept & application of Product Life Cycle (PLC), Sales & distribution Management. Different Between Small Scale & Large Scale Business, Market Survey, Method of marketing, Publicity and advertisement, Marketing Mix.	
3	**Institutions Support** Preparation of Project. Role of Various Schemes and Institutes for self-employment i.e. DIC, SIDA, SISI, NSIC, SIDO, Idea for financing/ non financing support agencies to familiarizes with the Policies /Programmes & procedure & the available scheme.	
4	**Investment Procurement** Project formation, Feasibility, Legal formalities i.e., Shop Act, Estimation & Costing, Investment procedure - Loan procurement - Banking Processes.	
	Productivity	
1	**Productivity** Definition, Necessity, Meaning of GDP.	

2	**Affecting Factors** Skills, Working Aids, Automation, Environment, Motivation How improves or slows down.	**10**
3	**Comparison with developed countries** Comparative productivity in developed countries (viz. Germany, Japan and Australia) in selected industries e.g. Manufacturing, Steel, Mining, Construction etc. Living standards of those countries, wages.	
4	**Personal Finance Management** Banking processes, Handling ATM, KYC registration, safe cash handling, Personal risk and Insurance.	
	Occupational Safety, Health & Environment Education	**15**
1	**Safety & Health** Introduction to Occupational Safety and Health importance of safety and health at workplace.	
2	**Occupational Hazards** Basic Hazards, Chemical Hazards, Vibroacoustic Hazards, Mechanical Hazards, Electrical Hazards, Thermal Hazards. Occupational health, Occupational hygienic, Occupational Diseases/ Disorders & its prevention.	
3	**Accident & safety** Basic principles for protective equipment. Accident Prevention techniques - control of accidents and safety measures.	
4	**First Aid** Care of injured & Sick at the workplaces, First-Aid & Transportation of sick person	
5	**Basic Provisions** Idea of basic provision legislation of India. of safety, health, welfare under legislation of India.	
6	**Ecosystem** Introduction to Environment. Relationship between Society and Environment, Ecosystem and Factors causing imbalance.	

7	**Pollution** Pollution and pollutants including liquid, gaseous, solid and hazardous waste.	
8	**Energy Conservation** Conservation of Energy, re-use and recycle.	
9	**Global warming** Global warming, climate change and Ozone layer depletion.	
10	**Ground Water** Hydrological cycle, ground and surface water, Conservation and Harvesting of water	
11	**Environment** Right attitude towards environment, Maintenance of in -house environment	
	Labour Welfare Legislation	**05**
1	**Welfare Acts** Benefits guaranteed under various acts- Factories Act, Apprenticeship Act, Employees State Insurance Act (ESI), Payment Wages Act, Employees Provident Fund Act, The Workmen's compensation Act.	
	Quality Tools	**10**
1	**Quality Consciousness :** Meaning of quality, Quality Characteristic	
2	**Quality Circles :** Definition, Advantage of small group activity, objectives of quality Circle, Roles and function of Quality Circles in Organization, Operation of Quality circle. Approaches to starting Quality Circles, Steps for continuation Quality Circles.	
3	**Quality Management System :** Idea of ISO 9000 and BIS systems and its importance in maintaining qualities.	
4	**House Keeping :** Purpose of Housekeeping, Practice of good Housekeeping.	
5	**Quality Tools** Basic quality tools with a few examples	

8.2 PRACTICAL TRAINING (ON-JOB TRAINING)

(BLOCK – I)

DURATION: 12 MONTHS

		GENERAL INFORMATION
1)	**Name of the Trade**	: **Laboratory Assistant – Immuno Diagnostics(Production /Manufacturing plant)**
2)	**Batch size**	: a) Apprentice selection as per Apprenticeship Guidelines.
3)	**Examination**	: i) The internal assessment will be held on Completion of the training duration. ii) LSC will be conducting exam at the end of training.

.4.**Instructors Qualification:**

i) Degree/Diploma in Pharmacy/Science (Biotechnology, Microbiology, Chemistry) or Master of Science from recognized university/Board with one/two year post qualification experience respectively in the relevant field.

OR

ii) LSC approved Material Handler with three year post qualification experience in the relevant field.

5. Infrastructure for On-Job Training: - As per Annexure–I

8.2.1 Syllabus for Practical Training/ On the Job Training Duration – 12 Months

1. Assembly Preparation for flow through
2. Solution Preparation - flow through.
3. Spotting of protein on nitrocellulose membrane(NCM) for flow through
4. Scanning of spotted device-flow through
5. Drying of spotted Device-flow through
6. Primary packing of dried spotted device-flow through
7. In process control during manufacturing of flow through device.
8. Do's and don’ts in flow through production
9. Solution Preparation – lateral flow.
10. Striping of protein on nitrocellulose membrane – lateral flow
11. Spraying of gold conjugate on polyester pad – lateral flow
12. Assembling of test card(sticking of various test component) lamination-lateral flow
13. Cutting of Assembled card in to test strip-lateral flow
14. Assembling of test strip in to cassettes-lateral flow
15. Primary packing of assembling device in Aluminium pouch-lateral flow
16. Primary packing of assembling dipsticks in Aluminium Blister pack-lateral flow
17. Do's and don’ts in lateral flow production
18. Cutting of HIPS sheet - SPIA
19. Solution preparation – SPIA
20. Spotting and drying process of antigen /antibody-SPIA
21. scanning of spotted – SPIA
22. Fixing process – SPIA
23. Blocking process – SPIA
24. Stabilizing process –SPIA
25. Drying process – SPIA
26. Packing of dried comb – SPIA
27. Sticking of Desiccant card – SPIA
28. Sticking of Arrow tape – SPIA
29. Cutting of comb in single test - SPIA
30. scanning of comb in single test – SPIA
31. Primary packing of single test comb in Aluminium Blisterpack-SPIA
32. Do's and don’ts in SPIA production
33. Solution preparation – Gold
34. Activation process of gold
35. Coupling process of gold
36. Concentration process of gold
37. Centrifugation process of gold
38. OD measurement of gold solution

39. Manufacturing process of comb based Gold
40. Manufacturing process of Flow through Gold
41. Manufacturing process of LFT Gold
42. Do's and don’ts in Gold production
43. Solution preparation of – ELISA
44. Coating of Antigen/ Antibody – ELISA
45. Blocking of Antigen/ Antibody – ELISA
46. Stabilizing of Antigen / Antibody – ELISA
47. Drying of ELISA plate.
48. Primary Packing of ELISA plate in to Aluminium pouch - ELISA

9. ASSESSMENT STANDARD

Assessment Guideline:

Appropriate arrangements should be made to ensure that there will be no artificial barriers to assessment. The nature of special needs should be taken into account while undertaking assessment. Due consideration to be given while assessing for team work, avoidance/reduction of scrape/wastage and disposal of scarp/wastage as per procedure, productivity, regulatory compliances, behavioural attitude and regularity in training.

The following marking pattern to be adopted while assessing:

a) Weightage in the range of 60-75% to be allotted during assessment under following Performance level:

For this grade, the candidate with occasional guidance and showing due regard for safety procedures and practices, has produced work which demonstrates attainment of an acceptable standard of craftsmanship.

In this work there is evidence of:

- Good skill levels in reagent manufacturing.
- Machine Handling
- Many tolerances while undertaking different work are in line with those demanded by the component/job.
- A fairly good level of neatness and consistency in the accuracy
- Occasional support in completing the project/job.

b) Weightage in the range of above75%- 90% to be allotted during assessment under following performance level:

For this grade, the candidate, with little guidance and showing due regard for safety procedures and practices, has produced work which demonstrates attainment of a reasonable standard of craftsmanship.

In this work there is evidence of

- Very Good skill levels in reagent manufacturing.
- Machine Handling with trouble shooting.
- Meeting exact tolerances while undertaking different work are in line with those demanded by the component/job.
- A fairly very good level of neatness and consistency in the inventory accuracy
- Rare support in completing the project/job.

c) Weightage in the range of above 90% to be allotted during assessment under Following performance level:

For performance in this grade, the candidate, with minimal or no support in organization and execution and with due regard for safety procedures and practices, has produced work which demonstrates attainment of a high standard of craftsmanship.

In this work there is evidence of:

- Very Good skill levels in reagent manufacturing.
- Machine Handling with trouble shooting and general basic maintenance.
- Meeting and exceeding tolerances level expectations while undertaking different work are in line with those demanded by the component/job.
- A high level of neatness and consistency in the inventory accuracy
- Minimal or No Rare support in completing the project/job.

10. FURTHER LEARNING PATHWAYS

Employment opportunities:

On successful completion of this course, the candidates may be gainfully employed in the following industries:

1. IVD Reagent Manufacturing Industry
2. IVD Lab Equipment manufacturing Industry
3. Bio - Pharma Companies

ANNEXURE – I

TOOLS & EQUIPMENT FOR BASIC TRAINING

INFRASTRUCTURE FOR PROFESSIONAL SKILL & PROFESSIONALKNOWLEDGE

TRADE: Laboratory Assistant – Immuno Diagnostics (Production PP/Manufacturing plant)

LIST OF TOOLS & EQUIPMENTS FOR 25 APPRENTICES

A : TRAINEES TOOL KIT:-

Sr. No.	Name of the items	Quantity (indicative)
1.	Safety Shoes	25 pairs
2.	Gown	25
3.	Gloves	25 pairs
4.	Ear Plugs	25 pairs
5.	SOP Charts	5
6.	Safety Norms Handbook	25
7.	Technical specification Sheet	1x 5sets (1 each per MHES type)
8.	Material Safety Data Sheet	25
9.	DO's and Don'ts Sheet	1x 5 sets (1 each per MHES Type)
	Equipment's	
1.	Robotic Dispenser I & J 7900- LF	8
2.	Comb Cutting Machine	5
3.	Isoflow Machine	2
4.	Vertical Laminar Air Flow Machine	4
5.	Label Printing Machine	4
6.	Product Container Washing Machine	2

7.	Ultrapure Water Siemens System	2
8.	Hot Plate Cum Stirrer (C-MAG HS7)	2
9.	Lyophilizer	1
10.	Bottle and Vial Filling Machine	2
11.	Automatic Aluminium Cap Sealing Machine	1
12.	Mechanical Stirrer	2
13.	Computers	7
14.	Software	7 Users

Note: In case of basic training setup by the industry the tools, equipment and machinery available in the industry may also be used for imparting basic training.

INFRASTRUCTURE FOR ON-JOB TRAINING

TRADE: Laboratory Assistant – Immuno Diagnostics (Production/Manufacturing plant)

Actual training will be conducted in the establishment using their own facility. It depends on the existing facilities available in the establishments. However, the industry should ensure that the broad skills defined against On-Job Training part (i.e. 12 months) are imparted. In case of any short fall the concern industry may impart the training in cluster mode/ any other industry to cover up the short fall.

ANNEXURE-II

GUIDELINES FOR INSTRUCTORS AND PAPER SETTERS

1. Due care to be taken for proper & inclusive delivery among the batch. Some of the following some method of delivery may be adopted:

A) LECTURE

B) LESSON

C) DEMONSTRATION

D) PRACTICE

E) GROUP DISCUSSION

F) DISCUSSION WITH PEER GROUP

G) PROJECT WORK

H) INDUSTRIAL VISIT

2. Maximum utilization of latest form of training viz., audio visual aids, integration of IT, etc. may be adopted.

3. The total hours to be devoted against each topic may be decided with due Diligence to safety & with prioritizing transfer of required skills.