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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Enforcement Division)

Date: 09 FEB 2024

CIRCULAR

Subject: Regulatory guidelines for sampling of drugs, cosmetics & medical devices by Drugs Inspectors of Central & State Drug Authorities - reg

In order to streamline and rationalize the sampling procedure of drugs, cosmetics & medical devices and maintaining a centralized monthly database of NSQ/Spurious drugs to publish on CDSCO Website, draft regulatory guidelines for sampling of drugs, cosmetics & medical devices by Drugs Inspectors of Central & State Drug Authorities was circulated to all zonal/sub zonal offices of CDSCO and State Licensing Authorities for their inputs and suggestions.

In this regard, the inputs/suggestions were received and has been incorporated appropriately in the guidance document. Copy of final guidance document is enclosed herewith for necessary implementation by Central & State Drug Authorities.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (I)

To,

1. All State Licensing Authorities
2. All Zonal/Sub Zonal offices of CDSCO
3. All State Drug Testing Laboratories
4. All Central Drug Testing Laboratories
5. CDSCO Website

REGULATORY GUIDELINES

FOR

SAMPLING OF DRUGS, COSMETICS & MEDICAL DEVICES BY DRUGS INSPECTORS OF CENTRAL & STATE DRUG AUTHORITIES

Version 01

Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health & Family Welfare

Government of India

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1. Introduction

Good quality medicines are essential for efficient disease management. Not of standard Quality (NSQ) and Spurious drugs can cause treatment failure and adverse reactions, increase morbidity and mortality, and contribute to the development of drug resistance. Vulnerable populations and patients with co-morbidities are at particular risk of being harmed from receiving substandard or spurious medicines. Poor-quality medicines also increase health care costs to both patients and the health system as a whole, wasting resources that could otherwise be used to benefit public health.

Drugs regulation in India is a complex process, where one side approval of new drugs, issuance of manufacturing license, wholesale license, retail license and their renewal/ retention are carried out by central and state regulatory authorities, which involves assessment of product technical documentation, inspection to ascertain manufacturers' compliance with the principles of Good Manufacturing Practices (GMP) and approval or issuance of approval & license as per Drugs & Cosmetics Act and Rules there under. Other side it also includes post-marketing surveillance (PMS) activities, such as maintenance of Market authorization/ registration through Post approval changes (PAC) for Biologicals, regular inspections of manufacturers, wholesalers and retailers, quality control testing, pharmacovigilance, routine sampling of products from the distribution channel and implementation of regulatory actions in the event of any quality problem reported to Drug Regulatory Authorities.

In general, sampling is carried out to assess the quality of drugs, cosmetic provided to patients and generate the data that can help to formulate strategies and plans to ensure the continuous availability of good quality products in the market. Sampling also confirms that patients are receiving satisfactory products and give reassurance that the regulatory system of the country is functional, or when there is a suspicion that patients are not receiving satisfactory medicines.

The Section 22 & 23 of the Drugs & Cosmetics Act 1940 prescribes the detail procedure for samples to be taken by Drugs Inspectors of Central and State drugs control as a part of routine drugs quality surveillance. Drugs sampling are costly tasks and limitations of resources may restrict the number of samples collected, parameters tested, techniques to be used for analysis or number of Drugs Inspector & Laboratory available to conduct the sampling and analysis respectively. Therefore, it is important to optimize the use of resources by focusing on drugs, cosmetic and parameters that pose a higher risk to patients and apply risk analysis during planning of the sampling.

From the past trends it is observed that there is no defined methodology for sample selection of drugs, cosmetic & location of sampling etc and being done randomly with the individual knowledge of Drug Inspectors. Often it is seen that sampled drugs are from big brands and collected from urban locations or sub urban locations only. The interior locations or rural distributions are not covered

and thereby quality of drugs at distant user/ last user is not being assessed. Cosmetics samples were not collected in some regions. There is no centralize database of sale outlets where NSQ / Spurious product were reported, such identified outlets are to be kept for regular vigilance.

The main objective of the sampling is to check the quality & efficacy of drugs & cosmetic available in the market with their approved specifications. This involves:

- Monitoring the quality of the API, Excipients and finished products of drugs, cosmetic and in all parts of the distribution chain throughout the authorised shelf-life.
- Ensuring that existing control methods are satisfactory.
- Investigating the Not of Standard Quality (NSQ) Product.
- Identifying Unapproved Products/ Without License sales outlets.
- Identifying Spurious drugs in distribution chain
- Identifying sales outlets where repetitive NSQ/ Spurious drugs are reported etc.

This guideline is mainly focused to utilize available information & identified risks for selection of sample & location to cover vast variety of drugs, cosmetic and medical devices moving in the market from manufacturing facility, wholesale outlet, retail outlet, government distribution channel etc. in urban, sub-urban, and rural locations. To maintain a centralized monthly NSQ/Spurious drug list and publishing on CDSCO website to avoid their further use.

This guideline will be useful for effective surveillance for quality & efficacy of drugs & cosmetic available in the market by adopting uniform drug sampling methodology for drugs inspectors under drug regulatory authorities of state and central.

2. Sampling Plan:

Each drugs inspector with consultation of his controlling authority shall prepare a sampling plan on monthly basis & annual basis for finalizing the sampling locations to cover the entire jurisdiction/ area under their office.This will avoid communication gap between the officers and optimum utilization of resource to cover the maximum territory and all kind of product category with identified risk and approached under this guidance document. Sampling plan should include rural/ tribal agency areas and drugs used in areas endemic for certain diseases, drugs for seasonal diseases. The annual sampling plan may be shared with their headquarters of their offices for review and to avoid any repetitive sampling of one brand and to cover maximum variety of brand/category in proposed sampling schedule.

3. Selection of sample:

The selection of sample will depend on various factors, which may indicate possible higher risk to the quality of drug. The Drugs Inspectors shall draw samples of different therapeutic categories,

different formulations, and different manufacturers from a one sales outlet by applying following identified risks, it is not exhaustive and is only indicative.

a. Feedback/information from citizens, Healthcare professionals. Products on which efficacy information is received during interaction with Doctors/Medical Representatives / Chemists / Pharmacists / Consumers / Media /Public Domain.
b. Sampling schedule provided by CDSCO for specific therapeutic category drugs in specific months (Yearly Joint Surprise Check schedule provided by CDSCO).
c. Use of Drugs Alert of CDSCO and State Drug Authorities for detail of frequent NSQ/ Spurious drugs and their manufacturing & sales outlets.
d. Seasonal changes in environmental conditions may have an influence on the quality of the medicine collected. It is possible that Spurious of antimalarial are more common during the malaria season.
e. Brands of the same product sold at different prices and aimed at different market segments.
f. Drugs found procured or sold at huge discounts (in deviation to ethical market practices)
g. Products with high consumption volumes.
h. Products having low potency and narrow therapeutic index.
i. Drugs found with tampered label.
j. Products which are sold during specific seasons or pandemic.
k. Information from various disease control programmes can be used like National Programs for De-worming, Universal vaccination etc.
l. Drugs manufactured by new manufacturers.
m. Products which are labeled / printed in suspicious manner. e.g. lack of required details, mistakes in spelling, illegible description etc.
n. Drugs with poor quality of primary packing (packing that comes indirect contact with the dosage form depending on the season and Products whose packing gives rise to suspicion of being low quality.
o. Products with one or more visible defects.
p. Brands which appears to be same/resemblance of other well-known or established brands.
q. Drugs for which proper purchase/sale record is not maintained (No purchase bills/ Batch Number or Date of Manufacturing or Expiry does not tally with the bill/ proper sale record not maintained especially if it is a wholesale concern).
r. Drugs that are usually sold/distributed to specific perceivably doctor attached counters and are not available in general counters.
s. Products which are in supply chain from different route other than regular/ authorize supply chain of manufacturer i.e. Super Stockiest – Stockiest – Wholesaler – Retailer.

t. Inter-State purchase by the whole seller or retailer and other than regular/ authorize supply chain of manufacturer.

The Drugs Inspector shall ensure that at least all the above identified risks are utilized in his sampling activities of 06 months. Further, not more than 03 samples are collected from one sale outlet and excess sampling, if any reasons shall be recorded and approved by the controlling authority.

4. **Selection of Sampling Location:**

The sampling location can be identified by applying following approaches; it is not exhaustive and is only indicative;

a. Frequent NSQ reports
b. Market complaints
c. Manufacturing and sales locations not yet sampled or last sampling was done more 01 years before by state or central drugs inspector.
d. Government Medical Store Depot.
e. Private/Public Sector manufacturing firms.
f. State, Central Government Hospitals/Institutes having local purchase by the Hospital/Institute.
g. Wholesale/Retail sales premises.
h. Sale outlets having operation in morning and evening hours only.
i. Sales outlet located nearby school & colleges.
j. Sales outlet situated at border areas of district, state, and country.
k. Prevalence of the disease in region & season for which the target medicines are indicated.
l. Complexity of manufacturing,
m. Stability of the medicine – risk of quality deterioration under local conditions of storage, distribution and use.
n. Non-Compliance of manufacturers of the target medicines with GMP principles.
o. Complexity of distribution chain for the target medicines and likelihood of non-compliance with good distribution practices (GDP) principles and approved storage conditions during distribution and storage.

5. Number of Samples:

Each Drugs Inspector shall collect samples under the provision specified in the Section 22 & 23 of the Drugs & Cosmetics Act 1940. Each Drugs Inspector shall collect at least 10 samples in a month comprising of following;

a. 09 samples of drugs (API, Excipient and Formulations)
b. 01 sample of cosmetics/ Medical Device.

6. Quantity of samples

It is important that sufficient quantity of samples are collected & forwarded to laboratory so that all the parameters are tested and re-testing, if any required by laboratory before issuing of NSQ test report. The quantity of samples also varies with type of samples like API, Formulations (Tablets, Capsules, Liquid Oral, Injectable, Large Volume Parenteral, Ointment, Lotions etc) and Cosmetics. Please refer **Annexure 1, 2, 3 and 4** for quantity required for testing of drugs samples, cosmetics samples, vaccine samples and biological samples respectively.

Sometime, retail outlets or rural sale outlet are not having sufficient quantity for complete testing and it become challenge to divide & pack sample in four equal portions. In this situation priority shall be given for tests like identification and assay under reduced testing to rule out spurious products. In such cases the sample portion can be divided in 02 equal portion preferably both with primary/secondary labels (one portion for Government analyst and other for producing in the court) and remaining 02 portions sufficient for performing reduced testing. This information shall be recorded in respective forms under Drugs & Cosmetics Rules and covering letter to respective Government Analyst, where sample is sent for testing for reduced testing i.e. identification and assay only due to non-availability of full quantity.

7. Timelines:

It is important to avoid any procedure delay in testing and obtaining of test report from the laboratory, so that further use of identified NSQ products are stopped by issuing drug alert and product recall notice at the earliest for public awareness, irrespective to proceeding of Drugs Inspector as per provision under Drugs & Cosmetic Act & Rules there under. Following timelines are to be followed;

a. The Drugs Inspector shall plan the sampling in such a way that samples are forwarded to laboratory on the same day of sampling.
b. If delay happens due to transit from rural location or distant location to office, then sample shall be forwarded to laboratory by next day and not later than that.
c. The disclosure under section 18A of Drugs & Cosmetics Act & Rules there under for Name, Address, copy of purchase invoice and other particulars of the person from whom he acquired the drug or cosmetic shall be obtained during sampling to rule out the possibility of Spurious drug. Further distribution chain establishment up to manufacturer level under section 18A of Drugs and Cosmetics Act is to be completed for all samples. This will be helpful to ensure the availability of true product in the market and also to initiate quick actions for NSQ product declared by the Government Analyst.
d. The Drugs Inspector shall obtain the method of analysis & reference/working standards from manufacturer for sample belongs to patent & proprietary drugs or new drugs, without

waiting for communication from laboratory and shall provide to the laboratory for timely testing of the product.

NOTE: CDSCO Drug Inspectors shall use SUGAM Lab Portal for generation of Form-17/ Form-17A/ Form-18 and forwarding through online (forms only) & offline (printed forms & samples) to the concerned laboratory.

8. Database / Monitoring:

Each Drugs Inspector shall maintain data of sampling and shall submit to their controlling authority on monthly basis for execution of sampling plan. The inputs from the monthly data of sampling shall be used for planning of next month's sampling plan. Following information are to be maintained;

a. Number of samples drawn and their process completion up to test report from laboratory and chain establishment up to manufacturer level.
b. Number of NSQs reported by laboratory and their action taken (Drugs Alert, Product Recall, Proposal to controlling Authority for Admin/Legal Action, Completed Action like Suspension /Cancellation of license, Court Cases Number etc.)
c. The cases of Spurious products reported by laboratory in test report or identified under chain establishment up to manufacturer by the Drugs Inspectors and their action taken (Drugs Alert indicating all the locations, Product Recall / Seizure, Number of Arrest, Proposal to controlling Authority for Legal Action, Court Cases No.).

Each Drug Controlling office shall prepare a list on monthly basis for Wholesale/retail outlet with name of registered pharmacist and owner where Spurious products are reported/ distribution chain is broken for the provided invoice.

The above list shall be shared to their head office for preparation of centralized list of wholesaler / retailer outlets revealed in sale/distribution of Spurious products and to give wide publicity for public to avoid use of purchased medicine from these outlets.

9. NSQ / Spurious Alerts:

The NSQ reports received from state and central laboratories shall be reported in excel sheet format as per **Annexure-6** with copy of test report preferably before 10th of every month for uploading at CDSCO website under Drug/Device/Cosmetic NSQ Alert for vide public awareness.

The samples identified as Spurious due to distribution chain breakage or reported by the manufacturer as Spurious shall be reported in excel sheet format as per **Annexure-7** with copy of Drugs Inspector report indicating distribution chain break with manufacturer response indicating how to identify original product from reported Spurious. The head of the field offices of

the State and central drug authorities shall forward the monthly spurious alert as per following excel sheet format for uploading at CDSCO website under Spurious Drug/Device/Cosmetic Alert for vide Public Awareness preferably before 10th of every month.

11. Testing Laboratories:

Detail of Notified laboratories for Drugs, Cosmetics and Medical device at central and state level is already available in Rules and notification/ letters circulated time to time.

States which are not having their own testing laboratories has notified Central Drugs Testing laboratories and Central labs are testing samples of state drugs inspectors.

In some quality complaint cases where state is neither have their own laboratory nor notified state laboratory for specific product category etc. requests the respective CDSCO field office for sampling by the CDSCO inspector for sampling.

Recently, G.S.R 409(E) dated 2nd June, 2023-Medical Devices (Amendment) Rules, 2023 "State medical Devices Testing Laboratory" means a medical devices laboratory established or designated by the State Government under sub-rule (3) of rule 19".

Central Medical Device Testing Laboratory (CMDTL) for testing of Medical Devices under MDR 2017. Total 6 CMDTL are notified by MOH&FW under MDR 2017 for testing of devices in the country as per S.O 2237(E) dated 1st June 2018.

Sr. No	Name of Laboratory	Category of medical device
1	The National Institute of Biologicals, Noida	In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent
2	The Central Drugs Testing laboratory, Chennai	Condoms
3	The Central Drugs Laboratory, Kolkata	Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant
4	The Regional Drugs Testing Laboratory (RDTL), Guwahati	Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets, I.V. Cannulae
5	The Central Drugs Testing Laboratory, Mumbai	Intra Uterine Devices (IUD) and Falope Rings
6	The Regional Drugs Testing Laboratory, Chandigarh	Disposable Hypodermic Syringes, Disposable Hypodermic Needles, Disposable Perfusion Sets, Catheters, I.V. Cannulae, Scalp Vein Set, Ligatures, Sutures, Staplers, Surgical Dressing, Umbilical Tapes.".

Revision History

Revision No.	Reason(s) for Revision
01	Inclusion of format for NSQ Alert for month (Annexure-6)
	Inclusion of format for Spurious Alert for month (Annexure-7)

Annexure-1

Quantity of Drugs Sample Required For Complete Analysis

S.No.	Name of Drug Sample	Form-18 Samples	Survey Samples
1.	Tablets	100 Tablets	20 Tablets
2.	Capsules	100 Capsules	20 Capsules
3.	Syrups / Oral Liquids/ Suspensions	12 Bottles	2 Bottles
4.	Injection (Ampoule) (1-10 ml)	40 Ampoules	10 Ampoules
	Injection (Ampoule) (10-100 ml)	25 Ampoules	10 Ampoules
5.	Large Volume Parentrals (more than 100 ml)	10 Bottles	2 Bottles
6.	Powder for injection (Sterile)	40 Vials	5 Vials
7.	Dry Powder for Oral/ Liquid Suspension	25 Bottles	5 Bottles
8.	Oral Rehydration Salt Sachets	30 Pcs	5 Pcs
9.	API Drug	2 x 10 gm	5 gm
10.	Ointment / Creams / Paste / Gel (Non Sterile)	12 Pcs	2Pcs
	Ointment / Creams / Paste / Gel (Sterile)	20pcs	5pcs
11.	Eye / Ear Drops	40 Vials/ pcs	5 Vials/ pcs
12.	Nasal Preparation	20 Vials	5 Vials
13.	Inhalers/ Spray	40 Pcs	5 Pcs
14.	Pessaries / Lozenges	60 Pcs	20 Pcs
15.	Empty Gelatine Capsules	500 Capsules	100 Capsules

Annexure-2

Quantity of Cosmetics Sample Required For Complete Analysis

S.N	Name of Cosmetic Sample	Form-18 Samples	Survey Samples
1.	Skin Cream	3 x 50 gm	1 x 50 gm
2.	Hair Cream	3 x 50 gm	1 x 50 gm
3.	Shampoo	3 x 200 ml	1 x 200 ml
4.	Soap	3 x 150 gm	1 x 150 gm
5.	Transparent Toilet Soap	3 x 150 gm	1 x 150 gm
6.	Tooth Powder	3 x 50 gm	1 x 50 gm
7.	Shaving Cream	3 x 15 gm	1 x 15 gm
8.	Cosmetic Pencil	20 Pencils	5 Pencils
9.	Hair Dyes (Liquid, Gel & Cream)	3 x 100 ml	1 x 100 ml
10.	Powder Hair Dyes	4 x 20 gm	1 x 20 gm
11.	Liquid Toilet Soap	3 x 100 ml	1 x 100 ml
12.	Bathing Bar	3 x 75 gm	1 x 75 gm
13.	Hair Oil	3 x 50 ml	1 x 50 ml
14.	Lipstick	15 Packs	5 Packs
15.	Nail Polish	15 Packs	5 Packs
16.	Talcum Skin powder	3 Packs	1 Packs
17.	Kajal	10 Packs	1 Packs
18.	Any other cosmetic	3 Packs	1 Packs

Annexure-3

Quantity of Vaccine Sample Required For Complete Analysis

S.N	Name of Vaccine Sample	Form-18 Samples
1.	Antitoxin / Anti Serum	10 ml x 10 vials / ampoules 1 ml x 50 vials / ampoules
2.	Anti-Snake Venom Serum / Anti Rabies Serum	10 ml x 5 vials / ampoules 5 ml x 10 vials / ampoules
3.	Bacterial Vaccine BCG	10 dose x 50 vials / ampoules/PFS 5 dose x 20 vials / ampoules 10 dose x 10 vials / ampoules 20 dose x 10 vials 10/20 dose x 40 vials
4.	Viral Vaccine OPV	1 dose x 50 vials/ampoules/PFS 5 doses x 20 vials/ ampoules 10 doses x 10 vials/ampoules 20 doses x 20 vials
5.	Blood Products	3 containers of 50 ml above 5 vials of 10 ml each 10 vials of 2 ml each 25 vials of 2 ml each 50 vials of 1 ml each
6.	Surgical Sutures	50 Strands

Annexure-4

Quantity of Biological / Medical Devices Samples

(*Note: List is for reference purpose only, however please check website of NIB, Noida for current information)

NEW CODE	PRODUCT NAME	QUANTITY REQUIRED/ BATCH	
		TESTING	RETAINED
A.1.1	Glucose Reagent-Open Ended Chemistry	500 ml or 1000 Tests with accessories	Nil
A.1.2	Glucose Reagent-Closed Chemisty System	1000 Tests or Reagent quantity enough for use over 25 working days vis-a-vis on-board shelf life of Reagent with accessories	Nil
A.2	Blood Glucose Test Strips	1200 Test Strips with accessories	350 Test Strips with accessories
A.3	Glucometer Device	10 Nos. with accessories	02 Nos. with accessories
B.1	ABD Pad	140 Tests	60 Tests
B.2	ABO confirmation card	144 Tests	72 Tests
B.3	ABO Rh Typing Card	144 Tests	72 Tests
B.4	Anti D (Verification of Weak D by IAT)	2 vials	1 vial
B.5	**Anti Kp^b Reagent	2 vials	1 vial
B.6	Anti-A (Bulk)	1vial	1 vial
B.7	Anti-A (Concentrate Bulk)	1vial	1 vial
B.8	**Anti-A /B / D /K / control ABO card	144 Tests	72 Tests
B.9	Anti-A Monoclonal	2 vials	1 vial
B.10	Anti-A_1 (Lectin)	2 vials	1 vial
B.11	Anti-AB (Monoclonal)	2 vials	1 vial
B.12	Anti-B (Concentrate Bulk)	1 vials	1 vial
B.13	Anti-B (Bulk)	1 vials	1 vial
B.14	Anti-B (Monoclonal)	2 vials	1 vial
B.15	**Anti-C^w Reagent	2 vials	1 vial
B.16	Anti-D (RH1) (Totem)	2 vials	1 vial
B.17	Anti-D (IgG) Monoclonal	2 vials	1 vial
B.18	Anti-D (IgM) Monoclonal	2 vials	1 vial
B.19	Anti-D (IgM)(Bulk)	1vial	1vial
B.20	Anti-D (IgM) (Concentrate Bulk)	1vial	1 vial
B.21	Anti-D (IgM+IgG) (Bulk)	1vial	1 vial
B.22	Anti-D (IgM+IgG) (Concentrate Bulk)	1vial	1 vial
B.23	Anti-D (IgM+IgG) Monoclonal	2 vials	1 vial
B.24	**Anti-Fy^a Reagent	2 vials	1 vial
B.25	**Anti-Fy^b Reagent	2 vials	1 vial
B.26	Anti-H (Lectin)	2 vials	1 vial
B.27	Anti-Human Globulin	2 vials	1 vial

B.28	**Anti-Jk^a Reagent	2 vials	1 vial
B.29	**Anti-Jk^b Reagent	2 vials	1 vial
B.30	**Anti-k Reagent	2 vials	1 vial
B.31	**Anti-K Reagent	2 vials	1 vial
B.32	**Anti-Kp^a Reagent	2 vials	1 vial
B.33	**Anti-Le^a Reagent	2 vials	1 vial
B.34	**Anti-Le^b Reagent	2 vials	1 vial
B.35	**Anti-M Reagent	2 vials	1 vial
B.36	**Anti-N Reagent	2 vials	1 vial
B.37	**Anti-P_i Reagent	2 vials	1 vial
B.38	**Anti-s Reagent	2 vials	1 vial
B.39	**Anti-S Reagent	2 vials	1 vial
B.40	Blood Grouping Cards	144 Tests	72 Tests
B.41	Blood Grouping Rapid Card Test	144 Tests	72 Tests
B.42	Bovine Serum Albumin	2 vials	1 vial
B.43	CombiPack ABD Monoclonal Antibody	2 combipack	1 combipack
B.44	**Gel Card Anti-M	144 Tests	72 Tests
B.45	**Gel Card Anti-N	144 Tests	72 Tests
B.46	Gel Card Anti-A_1 (Lectin)	144 Tests	72 Tests
B.47	**Gel Card Antigen Profile I	144 Tests	72 Tests
B.48	**Gel Card Antigen Profile II	144 Tests	72 Tests
B.49	**Gel Card Antigen Profile III	144 Tests	72 Tests
B.50	Gel Card Anti-H (Lectin)	144 Tests	72 Tests
B.51	Gel card for Direct Anti Globulin test	144 Tests	72 Tests
B.52	*Gel card for new born	144 Tests	72 Tests
B.53	Gel Card forward & reverse grouping	144 Tests	72 Tests
B.54	Gel Card forward grouping	144 Tests	72 Tests
B.55	Gel Card Rh Subgroups	144 Tests	72 Tests
B.56	*Gel Cards ABO/Rh for Newborns DVI Neg/Pos	144 Tests	72 Tests
B.57	Gel Cards Anti-A/B/AB/DVI Pos/ DVI Neg/Ctl	144 Tests	72 Tests
B.58	Gel Cards Anti-A/B/D/Rh subgroups	144 Tests	72 Tests
B.59	**Gel Cards Anti-C^w	144 Tests	72 Tests
B.60	Gel Cards Anti-D (Human)	144 Tests	72 Tests
B.61	Gel Cards Anti-DVI	144 Tests	72 Tests
B.62	**Gel Cards Anti Fy^a	144 Tests	72 Tests
B.63	**Gel Cards Anti Fy^b	144 Tests	72 Tests
B.64	**Gel Cards Anti Jk^a	144 Tests	72 Tests
B.65	**Gel Cards Anti Jk^b	144 Tests	72 Tests
B.66	**Gel Cards Anti K	144 Tests	72 Tests

B.67	**Gel Cards Anti-k	144 Tests	72 Tests
B.68	**Gel Cards Anti-Kp^a	144 Tests	72 Tests
B.69	**Gel Cards Anti-Kp^b	144 Tests	72 Tests
B.70	**Gel Cards Anti-Le^a	144 Tests	72 Tests
B.71	**Gel Cards Anti-Le^b	144 Tests	72 Tests
B.72	**Gel Cards Anti-Lu^a	144 Tests	72 Tests
B.73	**Gel Cards Anti-Lu^b	144 Tests	72 Tests
B.74	**Gel Cards Anti-Pi	144 Tests	72 Tests
B.75	**Gel Cards Anti-S	144 Tests	72 Tests
B.76	**Gel Cards Anti s	144 Tests	72 Tests
B.77	Gel Cards Crossmatch Testing (CT)	144 Tests	72 Tests
B.78	Gel Cards Neutral	144 Tests	72 Tests

B.79	**Gel Cards Rh subgroups + C^w + K	144 Tests	72 Tests
B.80	**Gel Cards Rh subgroups + K	144 Tests	72 Tests
B.81	Gel Cards Type + Screen	144 Tests	72 Tests
B.82	Microplate for forward & Reverse grouping	144 Tests	72 Tests
B.83	*Newborn casette for AntiA/AntiB/ Anti AB/ Anti D/ Control / Anti IgG	144 Tests	72 Tests
B.84	Sera/Gel Card for AHG & C3d	144 Tests	72 Tests
B.85	Gel cards for Anti-A, B, DVI-/Enzyme/AHG	144 Tests	72 Tests
B.86	Gel cards for DAT Anti-IgG-Dilution	144 Tests	72 Tests
B.87	Gel cards for LISS/ Coombs + Enzyme Test	144 Tests	72 Tests
B.88	Gel cards for DC-Screening I	144 Tests	72 Tests
B.89	Gel cards for Reverse Grouping with Antibody Screening	144 Tests	72 Tests
B.90	Anti-Human Globulin IgG	2 vials	1 vial
B.91	Anti-Human Globulin C3d	2 vials	1 vial
B.92	Rh Phenotype Card with Anti-D	144 Tests	72 Tests
B.93	Gel card for ABO/Rh for Patients	144 Tests	72 Tests
B.94	**Anti-Lu^a Reagent	2 vials	1 vial
B.95	**Anti-Lu^b Reagent	2 vials	1 vial

B.96	Starter pack for preparing Coombs Control Cells	2 Pack	1 Pack
B.97	Gel Card for DC Screening II	144 Tests	72 Tests
B.98	Gel Card for ABO Sub Grouping	144 Tests	72 Tests
C.1	Anti HBc IgM CLIA	150 Tests	150 Tests
C.2	Anti HBc IgM ELFA	150 Tests	150 Tests
C.3	Anti HBc IgM ELISA	96 Tests x 02 Kits	96 Tests x 02 Kits
C.4	HBe Ag CLIA	150 Tests	150 Tests

C.5	HBe Ag ELFA	150 Tests	150 Tests
C.6	HBe Ag ELISA	96 Tests x 02 Kits	96 Tests x 02 Kits
C.7	Anti HBs CLIA/HBs Ab CLIA	150 Tests	150 Tests
C.8	Anti HBs ELFA/HBs Ab ELFA	150 Tests	150 Tests
C.9	Anti HBs ELISA/HBs Ab ELISA	96 Tests x 02 Kits	96 Tests x 02 Kits
C.10	Anti-HBe CLIA/ HBe Ab CLIA	150 Tests	150 Tests
C.11	Anti-HBe ELFA/ HBe Ab ELFA	150 Tests	150 Tests
C.12	Anti-HBe ELISA/ HBe Ab ELISA	96 Tests x 02 Kits	96 Tests x 02 Kits
C.14	Dengue IgM ELISA	96 Tests x 02 Kits	96 Tests x 02 Kits
C.15	HBc IgM CLIA	150 Tests	150 Tests
C.16	HBc IgM ELFA	150 Tests	150 Tests
C.17	HBc IgM ELISA	96 Tests x 02 Kits	96 Tests x 02 Kits
C.18	HBc Total CLIA/ Anti HBc Total CLIA	150 Tests	150 Tests
C.19	HBc Total ELFA / Anti HBc Total ELFA	150 Tests	150 Tests
C.20	HBc Total ELISA/ Anti HBc Total ELISA	96 Tests x 02 Kits	96 Tests x 02 Kits
C.21	HBe Ag-Ab CLIA	250 Tests	250 Tests
C.22	HBe Ag-Ab ELFA	250 Tests	250 Tests
C.23	HBe Ag-Ab ELISA	96 Tests x 03 Kits	96 Tests x 03 Kits
C.24.1	HBsAg CLIA	700 Tests	700 Tests
C.24.2		400 Tests	400 Tests
C.25.1	HBsAg ELFA	700 Tests	700 Tests
C.25.2		400 Tests	400 Tests
C.26.1	HBsAg ELISA	96 Tests x 07 Kits	96 Tests x 07 Kits
C.26.2		96 Tests x 04 Kits	96 Tests x 04 Kits
C.27	HBsAg Confirmatory ELISA*****	100 Tests	100 Tests
C.28.1	HBsAg Rapid (Strip/Cassette) {Lateral Flow (Immunochromatography)}	600 Tests	600 Tests
C.28.2		250 Tests	250 Tests
C.29.1	HCV Ab CLIA	700 Tests	700 Tests
C.29.2		400 Tests	400 Tests
C.30.1	HCV Ab ELFA	700 Tests	700 Tests
C.30.2		400 Tests	400 Tests
C.31.1	HCV Ab ELISA	96 Tests x 07 Kits	96 Tests x 07 Kits
C.31.2		96 Tests x 04 Kits	96 Tests x 04 Kits
C.32	HCV Ab Confirmatory/ Supplemental Rapid	100 Tests	100 Tests
C.33.1	HCV Ab Rapid (Strip/Cassette) {Lateral Flow (Immunochromatography)}	600 Tests	600 Tests
C.33.2		250 Tests	250 Tests
C.34	HCV Ab RIBA	100 Tests	100 Tests

C.35	HCV Ab Confirmatory Western Blot	100 Tests	100 Tests
C.36.1	HCV Ag-Ab ELFA	700 Tests	700 Tests
C.36.2		400 Tests	400 Tests
C.37.1	HCV Ag-Ab ELISA	96 Tests x 07 Kits	96 Tests x 07 Kits
C.37.2		96 Tests x 04 Kits	96 Tests x 04 Kits
C.38.1	HIV 1&2 Ab CLIA	700 Tests	700 Tests
C.38.2		400 Tests	400 Tests
C.39.1	HIV 1&2 Ab ELFA	700 Tests	700 Tests
C.39.2		400 Tests	400 Tests
C.40.1	HIV 1&2 Ab ELISA	96 Tests x 07 Kits	96 Tests x 07 Kits
C.40.2		96 Tests x 04 Kits	96 Tests x 04 Kits
C.41	HIV 1&2 Ab Confirmatory/ HIV 1& 2 Ab Supplemental Rapid	100 Tests	100 Tests
C.42.1	HIV 1&2 Ab Rapid (Strip/Cassette) {Lateral Flow (Immunochromatogr aphy)}	600 Tests	600 Tests
C.42.2		250 Tests	250 Tests
C.43	HIV 1&2 Ab Confirmatory Western Blot	100 Tests	100 Tests
C.46.1	HIV Ag-Ab CLIA	700 Tests	700 Tests
C.46.2		400 Tests	400 Tests
C.47.1	HIV Ag-Ab ELFA	700 Tests	700 Tests
C.47.2		400 Tests	400 Tests
C.48.1	HIV Ag-Ab ELISA	96 Tests x 07 Kits	96 Tests x 07 Kits
C.48.2		96 Tests x 04 Kits	96 Tests x 04 Kits

C.49.1	HIV Ag-Ab Rapid (Strip/Cassette) {Lateral Flow (Immunochromatogr aphy)}	600 Tests	600 Tests
C.49.2		250 Tests	250 Tests
C.50.1	HIV TP Combo Rapid	700 Tests	700 Tests
C.50.2		350 Tests	350 Tests
C.51.1	HIV,HCV Combo Rapid	700 Tests	700 Tests
C.51.2		350 Tests	350 Tests
C.52.1	HIV,HCV,HBV Combo Rapid	800 Tests	800 Tests
C.52.2		450 Tests	450 Tests
C.54	Paclitaxel for HIV, HBsAg, HCV	01 Vial	01 Vial
C.55	Human Plasma/ Plasma Pool for Fractionation as per IP	03 Vials x 05 ml	03 Vials x 05 ml
C.56	Syphilis CLIA	300 Tests	300 Tests
C.57	Syphilis ELISA	96Tests x 03 Kits	96Tests x 03 Kits
C.58	Syphilis Rapid (Strip/Cassette) {Lateral Flow (Immunochromatogr aphy)}	250 Tests	250 Tests

C.59	Syphilis RPR	250 Tests	250 Tests
C.60	Syphilis TPHA	250 Tests	250 Tests
#C.61	Infection diagnostic test for HBV (Qualitative)	36 Tests	36 Tests
#C.62	Infection diagnostic test for HCV (Qualitative)	36 Tests	36 Tests
#C.63	Infection diagnostic test for HIV-1 (Qualitative)	98 Tests	98 Tests
#C.64	Blood donor Screening multiplex (HBV, HCV & HIV) Test (Qualitative)	146 Tests	146 Tests
#C.65	Viral load monitoring Kit for HBV	24 Tests	24 Tests
#C.66	Viral load monitoring Kit for HCV	24 Tests	24 Tests
#C.67	Viral load monitoring Kit for HIV-1	76 Tests	76 Tests
C.69.1	HIV, HCV, Syphilis and HBsAg Combo Rapid (Device having Four individual sample addition wells)	600 Tests	600 Tests
C.69.2		250 Tests	250 Tests
C.70.1	HIV 1&2 Ab Rapid (Strip/Cassette) {Vertical Flow (Immunofiltration)}	600 Tests	600 Tests
C.70.2		250 Tests	250 Tests
C.71.1	HIV 1+2 (Immunodot Test/ Dot Immuno Assay)	600 Tests	600 Tests
C.71.2		250 Tests	250 Tests
C.72.1	HIV Ag-Ab Rapid (Strip/Cassette) {Vertical Flow(Immunofiltration)}	600 Tests	600 Tests
C.72.2		250 Tests	250 Tests
C.73.1	HCV Ab Rapid (Strip/Cassette) {Vertical Flow (Immunofiltration)}	600 Tests	600 Tests
C.73.2		250 Tests	250 Tests
C.74	HBsAg Confirmatory CLIA**	100 Tests	100 Tests
D.1.1	Anti-D Immunoglobulin for Intravenous use	110 vials	60 vials
D.1.2		55 vials	30 vials
D.2.1	Anti-D (Rho) Immunoglobulin (Intramuscular)	50 vials	25 vials
D.2.2		100 vials	50 vials
D.3	Anti-Inhibitor Coagulant Complex	10 vials	05 vials
D.5.1	Hepatitis B	70 vials	40 vials
D.5.2		33 vials	25 vials

D.5.3	Immunoglobulin (Intramuscular)	18 vials	12 vials
D.5.4	Hepatitis B Immunoglobulin (subcutaneous)	70 vials	50 vials
D.6.1	Hepatitis B Immunoglobulin (Intravenous)	110 vials	60 vials
D.6.2		55 vials	30 vials
D.6.3		05 vials	02 vials
D.7	Human Albumin	04 Bottles	02 Bottles
D.8	Human Coagulation Factor - IX	06 vials	04 vials
D.9	Human Coagulation Factor - IX (recombinant)	06 vials	02 vials
D.10.1	Human Coagulation Factor - VIII (Dried Human Antihaemophilic Fraction)	08 vials	04 vials
D.10.2	Human Coagulation Factor - VIII (without vWF) (Dried Human Antihaemophilic Fraction)		
D.11	Human Normal Immunoglobulin (IM)	10 vials	05 vials
D.12	Human Normal Immunoglobulin (Intramuscular) (Bulk)	04 Bottles	02 Bottles
D.13.1	Human Normal Immunoglobulin for Intravenous use	03 Bottles	02 Bottles
D.13.2		10 Bottles	08 Bottles
D.13.3		03 Bottles	02 Bottles
D.14	Human Plasma Protein Fraction	04 Bottles	02 Bottles
D.15	Human Prothrombin Complex (PTC)	10 Bottles	05 Bottles
D.16	Human Normal/Specific Immunoglobulin (IV) (Bulk)	03 Bottles	03 Bottles
D.17	Rabies Immunoglobulin	20 vials	10 vials
D.18	Human Coagulation Factor-VIII (recombinant)	06 vials	02 vials
D.19	Tetanus Immunoglobulin (Intramuscular)	50 vials	25 vials
D.20	Tetanus Immunoglobulin (Intramuscular) (Bulk)	04 Bottles	02 Bottles
D.21	Human Fibrinogen	05 vials	02 vials

D.22	Human Normal Immunoglobulin (IgG) (subcutaneous administration)	04 bottles	02 Bottles
D.23.1	Fibrin Sealant Kit	06 Kits	02 Kits
D.23.2	Fibrin Sealant Kit (without F-XIII)		
D.23.3	Fibrin Sealant Kit (without Fibrinogen)		
D.24	Anti-T Lymphocyte Immunoglobulin for Human Use, Animal (lyophilized)	10 vials	10 vials
D.25	Antihemophilic Factor VIII (Recombinant PEGylated)	10 vials	10 vials
D.26	Anti-D Immunoglobulin (Intramuscular) Freeze Dried	50 vials	25 vials
E.1	Heparin Sodium injection	08 vials	06 vials
E.2	Human Chorionic Gonadotropin (HCG) Bulk	0.2g x 1 vial & 5mg x 5 vials *Sample is required in separate vials containing quantity as mentioned above	Nil

E.3.1	Human Chorionic Gonadotropin (HCG) injection	08 vials	06 vials
E.3.2		10 vials	07 vials
E.4	Menotropin (Human Menopausal Gonadotropin) Bulk	2mg x 4 vials, 4mg x 1 vial & 5mg x 2 vials *Sample is required in separate vials containing quantity as mentioned above	Nil
***E.5.1**	Menotropin (Human Menopausal Gonadotropin) injection	17 vials	14 vials
***E.5.2**		14 vials	14 vials
***E.5.3**		12 vials	10 vials
***E.5.4**		12 vials	10 vials
E.6.1	Enoxaparin Sodium Injection	20 vials	20 vials
E.6.2		18 vials	18 vials
E.7.1	Recombinant Human Growth Hormone/Somatropin injection	12 vials	10 vials
E.7.2			
E.7.3			
E.7.4			
E.7.5			
E.7.6			
E.7.7		12 PFS/Vial	10 PFS/Vial
E.8.	Recombinant Streptokinase injection	12 vials	10 vials
		10 PFS	10 PFS

E.9	Recombinant Human Follicle Stimulating Hormone Injection	10 vials	10 vials
E.10	Streptokinase Bulk	25mg x 3 vials, 5mg x 5 vials, 10mg x 2 vials & 15mg x 1 vial *Sample is required in separate vials containing quantity as mentioned above	Nil

*** E.11.1**	Streptokinase injection	10 vials	08 vials
*** E.11.2**		09 vials	08 vials
# E.12.1	Tenecteplase for injection (TNK-TPA)	6 vials	2 vials
# E.12.2		6 vials	2 vials
# E.12.3		6 vials	2 vials
E.13	Urofollitropin Bulk	5mg x 3 vials & 2mg x 2 vials *Sample is required in separate vials containing quantity as mentioned above	Nil
# E.14.1	Urofollitropin injection	11 vials	08 vials
# E.14.2		11 vials	08 vials
E.15	Urokinase Bulk/Final	05mg x 8 vials *Sample is required in separate vials containing quantity as mentioned above	Nil
# E.16	Urokinase injection	11 vials	08 vials
# E. 17	Elaprase Injection	04 vials	04 vials
# E.18	VPRIV Injection	06 vials	06 vials
# E. 19	Replagal Injection	04 vials	04 vials
E.20	Human C1-Esterase Inhibitor	13 vials	08 vials

F.1.1	Biphasic Isophane Insulin (25/75)	25	10
F.1.2	Biphasic Isophane Insulin (25/75)	15	10
F.1.3	Biphasic Isophane Insulin (30/70)	25	10
F.1.4	Biphasic Isophane Insulin (30/70)	15	10
F.1.5	Biphasic Isophane Insulin (50/50)	25	10
F.1.6	Biphasic Isophane Insulin (50/50)	15	10
F.2	Dulaglutide	25	5
F.3	Exenatide	25	5
F.4.1	Filgrastim Injection (rh. GCSF)	15	5
F.4.2		15	10
F.5	Insulin Aspart bulk	2g x 2 aliquotes	Nil
F.6.1	Insulin Aspart	25	10
F.6.2		15	10
F.7.1	Insulin Aspart & Insulin aspart protamine suspension Mixed in 30/70	25	10

	mix		
F.7.2	Insulin Aspart & Insulin aspart protamine suspension Mixed in 50/50 mix	25	10
F.8	Insulin Degludec	20	10
F.9	Insulin Degludec / Insulin Aspart	30	10
F.10	Insulin Detemir	20	10

F.11.1	Insulin Glargine	25	10
F.11.2		25	10
F.11.3		15	10
F.12.1	Insulin Glulisine	25	10
F.12.2		15	10
F.13	Insulin Lispro bulk	2g x 2 aliquotes	Nil
F.14.1	Insulin Lispro	25	10
F.14.2		15	10
F.15.1	Insulin Lispro & Insulin Lispro Protamine Suspension (Mixed in 25/75 Mix)	25	10
F.15.2	Insulin Lispro & Insulin Lispro Protamine Suspension Mixed in 50/50 Mix	25	10
F.16	Interferon alpha 2b injection	15	10
F.17.1	Isophane insulin (NPH)	25	10
F.17.2		15	10
F.18	Liraglutide (Glucagonlike Peptide-1)	20	10
F.19	Peg Filgrastim Injection (PegGCSF)	20	5
F.20	Peg Interferon alpha 2b inj	15	10
F.21	Peg Interferon Beta 1a inj	25	5
F.22	rh – Insulin bulk	2g x 2 aliquotes	Nil
F.23	rh- Erythropoietin bulk	2g x 2 aliquotes	Nil
F.24.1	rh. Erythropoietin injection	15	5
F.24.2		20	5
F.25	rh. Interferon beta 1a Injection	30	5

F.26.1	Soluble insulin (Regular)	25	10
F.26.2		15	10
F.27	Teriparatide (rh. Para Thyroid Hormone-PTH)	15	10
F.28	Xultophy (Liraglutide & Degludec)	30	10
F.29	Peg Erythropoietin	20	10
F.30.1	Peg Interferon Beta 1a inj	30	5
F.30.2		30	5
F.31	Insulin Glargine Bulk	2g x 2 aliquotes	Nil

F.32	Recombinant interferon beta 1binjection 250 µg/ ml	20 vials	5 vials
F.33	Darbepoetin Alpha Injection	25 vials	5 vials
H.1	Cell Culture Rabies vaccine	21 vials	10 vials
H.2.1	Hepatitis A	20 vials	20 vials
H.2.2		12 vials	12 vials
H.3.1	Hepatitits B	20 vials	20 vials
H.3.2		12 vials	12 vials
H.3.3		12 vials	12 vials
H.4	Japanese Encephalitis Vaccine(Human)	20 vials	20 vials
H.5.1	Measles Mumps & Rubella Vaccine	20 vials	20 vials
H.5.2		14 vials	14 vials
H.6.1	Measles Vaccine	20 vials	20 vials
H.6.2		14 vials	14 vials
H.7.1	Rubella vaccine	20 vials	20 vials
H.7.2		14 vials	14 vials
H.8	Bacillus Calmette Guerin (BCG)Vaccine	57 vials	57 vials

H.9.1	Haemophilus Influenzae Type-b-(Hib)-TT Conjugate Vaccine	55 vials	55 vials
H.9.2		18 vials	18 vials
H.10	Oral Cholera Vaccine	20 vials	20vials
H.11	Oral Polio Vaccine	10 vials	10 vials
H.12.1	COVID-19 Vaccines (Covishield, Covaxin, ZyCoV-D)	40 vials	20 vials
H.12.2		10 vials	5 vials
H.12.3		10 vials	5 vials
H.13	Rabies Immunoglobulin (Equine)	20 vials	10 vials
H.14	Human Papilloma Virus Vaccine(r-DNA)	30 vials	15 vials
J.1.1	Adalimumab	10 PFS	10 PFS
J.1.2		11 PFS	11 PFS
J.1.3		10 PFS	10 PFS
J.2.1	Bevacizumab	5 vials	5 vials
J.2.2		5 vials	5 vials
J.3	Etarnercept	9 PFS	9 PFS
J.4	Pertuzumab	5 vials	5 vials
J.5.1	Ramucirumab	5 vials	5 vials
J.5.2		5 vials	5 vials
J.6	Ranibizumab	16 vials	16 vials
J.7.1	Rituximab	5 vials	5 vials
J.7.2		5 vials	5 vials
J.8.1	Trastuzumab	6 vials	6 vials
J.8.2		6 vials	6 vials

J.9.1	Anti-D Immunoglobulin, I.M (Monoclonal)	33 vials	33 vials
J.9.2		36 vials	36 vials
J.10.1	Human Hepatitis B Immunoglobulin (Intramuscular)	50 vials	50 vials
J.10.2		33 vials	33 vials
J.10.3		18 vials	18 vials
J.10.4		13 vials	13 vials
J.10.5		6 vials	6 vials

J.10.6	(Monoclonal)	3 vials	3 vials
J.12.1	Tetanus Immunoglobulin (Monoclonal), Tetclone	33 vials	33 vials
J.12.2		18 vials	18 vials
J.13	Obinutuzumab	4 vials	4 vials
J.14	Omalizumab	9 vials	9 vials
J.15	Natalizumab	4 vials	4 vials
J.16	Pembrolizumab	4 vials	4 vials
J.17	Infliximab	10vials	10Vials
J.18	Mepolizumab	10vials	10Vials
J.19	Recombinant Anti Rho-D Immunoglobulin Injection	100 vials	100 vials
J.20	Vedolizumab	09 vials	09 vials
J.21.1	Transtuzumab Emtansine	05 vials	05 vials
J.21.2		05 vials	05 vials
J.22	Inotuzumab Ozogamicin (Powder for solution for infusion)	10vials	10Vials
J.23.1	Denosumab	12 PFS	12 PFS
J.23.2		12 vials	12 vials
J.24	Benralizumab	12 PFS	12 PFS
J.25.1	Durvalumab	09 vials	09 vials
J.25.2		05 vials	05 vials
J.26	Tocilizumab	05 vials	05 vials
J.27	Cetuximab	05 vials	05 vials

J.28	Brentuximab Vedotin	09 vials	09 vials
J.29	Evolocumab Injection	15 PFS	15 PFS
J.30	Nivolumab	09 vials	09 vials
J.31	Secukinumab	15 vials	15 vials
K.1	RT-PCR Kits for Diagnosis of COVID-19 (Validation)	160 Tests	160 Tests
K.2	RT-PCR Kits for Diagnosis of COVID-19 (Batch Testing)	50 Tests	50 Tests
K.3	RNA Extraction Kits for Diagnosis of COVID-19 (Validaton)	50 Tests	50 Tests
K.4	RNA Extraction Kits for Diagnosis of COVID-19 (Batch Testing)	30 Tests	30 Tests
K.5	VTM for Diagnosis of COVID-19 (Validation)	20 Tests	20 Tests
K.6	VTM for Diagnosis of COVID-19 (Batch Testing)	10 Tests	10 Tests
K.7	COVID Ab kit (IgG to S Protein) Rapid	250 Tests	250 Tests
K.8	COVID Ab kit (IgG to S Protein) CLIA	400 Tests	400 Tests
K.9	COVID Ab kit (IgG to N Protein) Rapid	250 Tests	250 Tests

K.10	COVID Ab kit (IgG to N Protein) CLIA	400 Tests	400 Tests
K.11	RT-LAMP Kit for Diagnosis of COVID-19 (Validation)	160 Tests	160 Tests
K.12	RT-LAMP Kit for Diagnosis of COVID-19 (Batch Testing)	50 Tests	50 Tests

Annexure-5

Quantity required for Complete Analysis of Medical Device Samples

S.No	Name of Medical Device	Form-18 Samples	Survey Samples
1.	Hypodermic Syringe	50pcs	10 pcs
2.	Hypodermic Needle/Disposable Syringe Needles	50 pcs	10 pcs
3.	Infusion Set/Transfusion Set	50 pcs	10 pcs
4.	IV Cannulas	50 pcs	10 pcs
5.	Roll Bandage/Surgical Dressings	20 pcs	10 pcs
6.	Sterile Gauze Swab	50 pcs	10 pcs
7.	Surgical Suture (absorbable)	50 pcs	30 pcs
8.	Surgical Suture (Non-absorbable)	50 pcs	30 pcs
9.	Medicated Tape (Band-aid)	100 pcs	20 pcs
10.	Absorbent Cotton Wool I.P.	200gm	100gm
11.	Catheter or Ryles Tube	30 pcs	10 pcs
12.	Tubing for Micros-surgery or Endoscope	50 pcs	10 pcs
13.	Male Rubber Latex Condoms	100 pcs	100 pcs
14.	Copper T	120 pcs	20 pcs
15.	Tubal Rings	100 pcs	20 pcs
16.	Blood Bags	10bags	5bags
17.	Absorbent Sponge	50 pcs	5 pcs

Annexure-6

NSQ Alert for month……

Sr. no. (1)	Product Type (2)	Name of product (3)	Brand Name (4)	Dosage Form (5)	Route (6)	NSQ Keyword (7)	Manufacturer Name (8)	Manufactured By (9)

Manufacturing State (10)	Manufacturing Date (11)	Expiry Date (12)	Reporting Source (13)	Reported by Lab/State (14)	Reporting Month & Year (15)	Batch No (16)	NSQ Result (17)	Modified Dosage Form (if applicable) (18)

Annexure-7

Spurious Alert for month……

List of Drugs, Medical Devices, Vaccine and Cosmetics declared as Spurious for the Month of ____

As part of the continuous regulatory surveillance, drugs samples are picked from sales/distribution point, analysed and list of spurious drugs are displayed on CDSCO portal on monthly basis. The purpose of displaying the spurious drugs list is to make stakeholders aware about the spurious drug batches identified in the market.

S. No.	Name of Drugs/medical device/cosmetics	Batch No.	Date of Manufacture	Date of Expiry	Manufactured By	Reason for failure	Drawn By	Firm's reply	Remarks
1.					Under Investigation			The actual manufacturer (as per label claim) has informed that the impugned batch of the product has not been manufactured by them and that it is a spurious drug.	The product is purported to be spurious, however, the same is subject to outcome of investigation.

Spurious Drugs: A drug shall be deemed to be spurious;

a. If it is manufactured under a name which belongs to another drug; or
b. if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
c. If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
d. If it has been substituted wholly or in part by another drug or substance; or
e. If it purports to be the product of a manufacturer of whom it is not truly a product.

(The term "Spurious Drug" has been defined under Section 17-B of the Drugs and Cosmetics Act, 1940)