

## Rapid Analytical Food Testing (RAFT) Kit/Equipment/Method

In its 27<sup>th</sup> meeting held on 04.02.2019, the Food Authority had approved the notification of Draft amendment to FSS (Laboratory and sample analysis) Regulation, 2011 and the proposal for operationalization of the said amendment. Following clause was inserted in the *ibid* regulations-

- 2.4 Approval of Rapid Analytical Food testing Kit, Equipment or Method-
- 2.4.1 Food Authority may approve Rapid Analytical Food testing Kit, Equipment or Methods for the purpose of testing of Food.
- 2.4.2 The procedure for approval of Rapid Analytical Food testing Kit, Equipment or Methods shall be as per the guidelines that may be framed by the Food Authority from time to time.

Thereafter, a direction was issued under section 16(5) vide letter no. 01/Lab & sample Analysis/Reg/2019 dated 05.07.2019 regarding operationalization of the aforesaid Regulations.

In the meantime, a notice dated 19.03.2019 alongwith the Application Form was uploaded on FSSAI's website seeking applications from desirous manufacturers/ method developers to apply for approval of their rapid testing kit/equipment/method. In response, a total of 55 RAFT Applications were received and placed before the Methods Review Group of FSSAI for scrutiny. The recommendations of the Methods Review Group have been endorsed by the Scientific panel on Methods of Sampling & Analysis and the Food Authority. After approval by the Competent Authority, a status of the scrutiny and recommendations is as under-

S. No.	Applicant	Rapid food testing kit/equipment/ method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
<b>Applications recommended for final approval (20)</b>				
1.	IDEXX Laboratories Pvt. Ltd.	Rapid food testing kit/media - Colilert & Colilert-18	Analytical testing of total coliform and <i>E. Coli</i> in drinking water	Recommended for Final Approval. The kit has been approved in several countries and the Method is an AOAC method as Rapid food testing kit for detection of <i>E. coli</i> , and <i>Coliforms</i> in Drinking water. Verification not required.
2.	IDEXX Laboratories Pvt. Ltd.	Rapid food testing kit/media - Pseudalert	Analytical testing of <i>Pseudomonas aeruginosa</i> in drinking water	Recommended for Final Approval. The kit is robust and validated and PSEUDALERT is recommended for use to detect <i>Pseudomonas aeruginosa</i> in drinking water. Verification not required.
3.	Nissui Pharmaceu-	Rapid food testing	Enumeration of	Recommended for final approval.

S. No.	Applicant	Rapid food testing kit/equipment/method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
	ticals	kit/media – Compact Dry ( <i>Coliforms</i> )	<i>Coliforms</i> - Food products testing, Specifically for rapid microbial testing of raw and finished food, water	The compact media has all necessary approvals and validations in food matrices as per FSSR. Hence, verification by laboratories is not recommended.
4.	Nissui Pharmaceuticals	Rapid food testing kit/media – Compact Dry ( <i>E. Coli</i> )	Enumeration of <i>E. Coli</i> - Food products testing, Specifically for rapid microbial testing of raw and finished food, water	Recommended for final approval. The compact media has all necessary approvals and validations in food matrices as per FSSR. Hence, verification by laboratories is not recommended.
5.	Nissui Pharmaceuticals	Rapid food testing kit/media – Compact Dry (Total Plate Count)	Enumeration of Total Count- Food products testing, Specifically for rapid microbial testing of raw and finished food, water	Recommended for final approval. The compact media has all necessary approvals and validations in food matrices as per FSSR. Hence, verification by laboratories is not recommended.
6.	Nissui Pharmaceuticals	Rapid food testing kit/media – Compact Dry ( <i>Bacillus cereus</i> )	Enumeration of <i>Bacillus cereus</i> - Food products testing, Specifically for rapid microbial testing of raw and finished food, water	Recommended for final approval. The compact media has all necessary approvals and validations in food matrices as per FSSR. Hence, verification by laboratories is not recommended.
7.	Nissui Pharmaceuticals	Rapid food testing kit/media – Compact Dry ( <i>Staphylococcus aureus</i> )	Enumeration of <i>Staphylococcus aureus</i> - Food products testing, Specifically for rapid microbial testing of raw and finished food, water	Recommended for final approval. The compact media has all necessary approvals and validations in food matrices as per FSSR. Hence, verification by laboratories is not recommended.
8.	Nissui Pharmaceuticals	Rapid food testing kit/media – Compact Dry ( <i>Yeast and Mold</i> )	Enumeration of <i>Yeast and Mold</i> - Food products testing,	Recommended for final approval. The compact media has all necessary approvals and

S. No.	Applicant	Rapid food testing kit/equipment/method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
			Specifically for rapid microbial testing of raw and finished food, water	validations in food matrices as per FSSR. Hence, verification by laboratories is not recommended.
9.	Biomerieux S.A	Rapid Equipment – Vitek 2 Compact	Automated system for species level microbial identification	Recommended for final approval. The equipment has all necessary approvals and validations in food matrices as per FSSR. Hence, verification by laboratories is not recommended.
10.	Biomerieux S.A	Rapid food testing media – Chromogenic Agar Media	Chromogenic media for simultaneous culture and confirmation of microorganisms or for simultaneous culture and presumptive identification for both detection and enumeration	Recommended for final approval if the followed isolation protocol (AOAC/ISO/BAM) recommends its use.
11.	Biomerieux S.A	Rapid food testing kit/ media – Analytical Profile Index	Microbial confirmation/ identification using API Strips	API strips are recommended for final approval only for biochemical confirmation of presumptive isolates. Also, recommended as an additional tool for rapid biochemical identification of bacteria provided the isolation method (AOAC/ISO/BAM) approves its use.
12.	3M India Limited	Rapid food testing kit/ media – Petrifilm(3M™ Petrifilm™ <i>E.coli/Coliform</i> (EC) Count Plate)	Testing of <i>E.coli/Coliform</i> in food products	Recommended for final approval for Meat and Meat Products, Fish and Fish Products. The kit/media has all necessary approvals and validations in these food matrices. Hence, verification by laboratories

S. No.	Applicant	Rapid food testing kit/equipment/method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
				is not recommended.
13.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ Rapid <i>E. coli</i> Count (REC) Plate)	Microbiology testing in food products	Recommended for final approval for Meat and Meat Products, Fish and Fish Products. The kit/media has all necessary approvals and validations in these food matrices. Hence, verification by laboratories is not recommended.
14.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ <i>Enterobacteriaceae</i> (EB) Count Plate)	Enumeration of <i>Enterobacteriaceae</i> Count in food products	Recommended for final approval for Milk and Milk Products, Fruits and Vegetables. The kit/media has all necessary approvals and validations in these food matrices. Hence, verification by laboratories is not recommended.
15.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ <i>Coliform</i> Count (CC) Plates)	Enumeration of <i>Coliform</i> Count in food products	Recommended for final approval for Milk and Milk Products. The kit/media has all necessary approvals and validations in this food matrix. Hence, verification by laboratories is not recommended.
16.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ Rapid <i>Coliform</i> Count (RCC) Plates)	Enumeration of <i>Coliform</i> Count in food products	Recommended for final approval for Milk and Milk Products. The kit/media has all necessary approvals and validations in this food matrix. Hence, verification by laboratories is not recommended.
17.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ Aerobic Count (AC) Plates)	Enumeration of Aerobic Count in food products	Recommended for final approval for Milk and Milk Products, Meat and Meat Products, Fish and Fish Products, Fruits and Vegetables. The kit/media has all necessary approvals and validations in these food

S. No.	Applicant	Rapid food testing kit/equipment/method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
				matrices. Hence, verification by laboratories is not recommended.
18.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ Rapid Aerobic (RAC) Count Plates)	Enumeration of Aerobic Count in food products	Recommended for final approval for Milk and Milk Products, Meat and Meat Products, Fish and Fish Products, Fruits and Vegetables. The kit/media has all necessary approvals and validations in these food matrices. Hence, verification by laboratories is not recommended.
19.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ Yeast & Mold (YM) Count Plates)	Enumeration of Yeast and Mold Count in food products	Recommended for final approval for Milk and Milk Products, Meat and Meat Products, Fish and Fish Products, Fruits and Vegetables. The kit/media has all necessary approvals and validations in these food matrices. Hence, verification by laboratories is not recommended.
20.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ Staph Express (STX) Count Plate + Disks)	Enumeration of <i>Staphylococcus aureus</i> in food products	Recommended for final approval for Milk and Milk Products, Meat and Meat Products, Fish and Fish Products, Fruits and Vegetables. The kit/media has all necessary approvals and validations in these food matrices. Hence, verification by laboratories is not recommended.
<b>Applications recommended for provisional approval (11)</b>				
1.	Oak Analytics India Pvt. Ltd.	Rapid equipment – RAMAN – 1	Detection of Economically Driven Adulteration (20% And Above) In Edible Oils And Fats	Provisionally approved. Labs identified for verification- (i) FARE Labs, Gurugram (ii) Referral Lab, IICT, Hyderabad (iii) Referral Lab, CFTRI, Mysore

S. No.	Applicant	Rapid food testing kit/equipment/method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
2.	DNA Diagnostic	Rapid food testing kit/media – Salmonella Velox	Salmonella detection in meat, fish and poultry products	Provisionally approved. Labs identified for verification- (i) CIFT, Kochi for fish and fish products (ii) NRC-Meat, Hyderabad for poultry and meat products
3.	Indifoss Analytical Pvt. Ltd.	Rapid food testing kit and equipment – Bioeasy	Aflatoxin M1 Raw Milk (Quantitative)	Provisionally approved. Labs identified for verification- (i) Centre for Analysis and Learning in Live stock and Food, National Dairy Development Board, Anand (ii) NDRI, Karnal
4.	Anton Paar India Pvt. Ltd.	Rapid equipment – Alcolyzer ME-Analysis System	Laboratory Alcohol analyzing system to directly measure ethanol content as well as other parameters of alcoholic beverages, without need of sample distillation	Provisionally approved. Labs identified for verification- (i) Vimta Labs Ltd., Hyderabad (ii) NRC Grapes, Pune
5.	Neogen Food & Animal Security (India) Private Limited	Rapid food testing kit/ media – Raptor Integrated Analysis Platform – Reveal Q+ Max	Aflatoxin (B1,B2,G1,G2) in nuts and nuts products (Corn, Almond, Walnuts, Peanut and Pistachios). Mycotoxin in all foods	Provisionally approved for Total Aflatoxin in Nuts, Peanuts and Corn only. Labs identified for verification- (i) ICAR-National Research Centre for Grapes- NRL for Mycotoxins (ii) Export Inspection Agency, Kochi
6.	Neogen Food & Animal Security (India) Private Limited	Rapid food testing kit/ media – Reveal 2.0	Pathogen screening [ <i>Salmonella</i> , <i>Listeria</i> & <i>E.Coli</i> O157:H7] test system	Provisionally approved for Reveal 2.0 only for Salmonella kit. Labs identified for verification- (i) NDRI, Karnal (ii) CIFT, Kochi
7.	Unisensor	Rapid Food Testing Kit and Equipment – Extenso Kit 075/Kit	Milk testing for veterinary drug residues	Provisionally approved. Labs identified for verification- (i) Centre for Analysis and

S. No.	Applicant	Rapid food testing kit/equipment/method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
		275		Learning in Live stock and Food, National Dairy Development Board, Anand (ii) Export Inspection Agency, Mumbai
8.	Biomerieux S.A	Rapid Equipment – Vidas (Tempo)	Automated system for microbial enumeration in food matrices	Tempo AC and Tempo EC are recommended for provisional approval subject to validation in different matrices as per FSSR. Labs identified for verification- (i) CIFT, Kochi (ii) EIA, Kochi (iii) CFL, Kolkata
9.	Biomerieux S.A	Rapid Equipment – Gene UP	Automated molecular system for rapid detection of Pathogens & Viruses in food matrices	Recommended for provisional approval subject to verification for rapid detection of <i>Salmonella</i> , <i>Listeria monocytogenes</i> , <i>E. Coli</i> 0157:H7 and <i>Cronobacterspp</i> for all matrices as per Appendix B of FSSR (Table 1 to 5). Labs identified for verification- (i) CIFT, Kochi –for Fish and Fish Products (ii) EIA, Cochin- Fruits & Vegetables and their products (iii) NDDB, Anand - Milk and Milk Products (iv) NRC, Meat- Meat and Meat Products (v) PBTL, Mohali – Water and Spices
10.	Biomerieux S.A	Rapid Equipment – Vidas	Automated system for rapid detection of Pathogens in food matrices	VIDAS UP <i>Salmonella</i> (SPT) and VIDAS <i>Listeria monocytogenes</i> express (LMX) are recommended for provisional approval. Labs identified for verification- (i) CIFT, Kochi (ii) EIA, Kochi (iii) CFL, Kolkata



S. No.	Applicant	Rapid food testing kit/equipment/ method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
11.	3M India Limited	Rapid food testing kit/ media – Petrifilm (3M™ Petrifilm™ Rapid Yeast & Mold (RYM) Count Plates)	Enumeration of <i>Yeast and Mold</i> Count in food products	Recommended for provisional approval for Milk and Milk Products, Meat and Meat Products, Fruits and Vegetables. Verification by laboratories required for dried/ salted fish and fish products- (i) CIFT, Kochi (ii) EIA, Kochi (iii) CFL, Kolkata
<b>Applications Not Approved (24)</b>				
1.	Indifoss Analytical Pvt. Ltd.	Rapid food testing kit and equipment – Bioeasy	Antibiotic Residues in Raw Milk (Qualitative only)	Not Recommended. Pending clarification from the applicant.
2.	Indifoss Analytical Pvt. Ltd.	Rapid food testing kit and equipment – Bioeasy	Aflatoxin M1 Raw Milk (Qualitative only)	Not Recommended. Not suitable for India: As it is a qualitative method, the screening detection limit should have been at least half of the ML (0.5ppb).
3.	Anton Paar India Pvt. Ltd.	Rapid equipment – Snap 51-Portable Alcohol meter	Alcoholic concentration measurement in alcoholic beverages	Not Recommended. This instrument does not come under the purview of the RAFT but may be used as a hand held device in mobile food testing laboratories. It is a general instrument and shall be used after calibration.
4.	Neogen Food & Animal Security (India) Private Limited	Rapid food testing kit/ media - Betastar S Test	Antibiotics in Milk	Not Recommended. The kit is presently not having any approval, has not been validated by international bodies, antibiotics in milk considered for validation as not covering the requirement as per FSSR (contaminants and residues).
5.	Neogen Food & Animal Security (India) Private Limited	Rapid food testing kit/ media – Soleris Rapid microbiology system	Alternative method for microbiology testing of foods (Raw/ Processed)	Not Recommended. Current FSSR does not require qualitative testing for APC, Yeast and Mold count, coliforms and E coli. Hence not suitable at this



S. No.	Applicant	Rapid food testing kit/equipment/ method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
				junction.
6.	Mettler-Toledo India Private Limited	Rapid equipment – Densito	Density/ Specific gravity/ Brix measurement	Not Recommended. This instrument does not come under the purview of the RAFT. This is a standard instrument for measurement of density and brix.
7.	Mettler-Toledo India Private Limited	Rapid equipment – S2 pH meter	pH measurement	Not Recommended. This instrument does not come under the purview of the RAFT. This is a standard instrument for measurement of pH.
8.	Mettler-Toledo India Private Limited	Rapid equipment – Refracto 30 PX/ Refracto 30 GS	Refractive index/ Brix measurement	Not Recommended. This instrument does not come under the purview of the RAFT. This is a standard instrument for measurement of Refractive Index and brix.
9.	Ilishaan Biotech Private Ltd.	Rapid Food Testing Kit – LSY 20103 – BTS Combo Rapid Test Strip	Rapid screening of Antibiotic in Raw Coumingled milk	Not Recommended. The kit does not cover all the Antibiotics residues as per the requirements laid down in FSSR.
10.	Delmos Research Pvt. Ltd.	Rapid food testing kit/ media – Delstrips, Rapid Kit for Detection of adulteration in milk	Detection of Adulteration in Milk	Not Recommended. The kit is only validated for maltodextrin with the condition that there is no interference from glucose, starch and hydrogen peroxide). Claim is for many adulterants, for which no validation document is submitted.
11.	National Dairy Development Board	Rapid food testing kit/ media – Kit for detection of adulterants in milk	Testing of raw/ processed milk for 9 possible adulterants	Not Recommended. Pending clarification and correction in application.
12.	DSM India Private Limited	Rapid food testing kit/ media - Delvotest <sup>®</sup> SP NT	Detect presence of Antibiotic Residues in Milk and Milk Products	Not Recommended. Does not cover the list of targeted antibiotic residues in milk.
13.	DSM India Private Limited	Rapid food testing kit/ media - Delvotest <sup>®</sup> T	Detect presence of Antibiotic Residues in Milk and Milk Products	Not Recommended. Does not cover the list of targeted antibiotic residues in milk.

S. No.	Applicant	Rapid food testing kit/equipment/ method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
14.	DSM India Private Limited	Rapid food testing kit/ media - Delvotest <sup>®</sup> Fast BL	Detect presence of Antibiotic Residues in Milk and Milk Products	Not Recommended. Does not cover the list of targeted antibiotic residues in milk.
15.	DSM India Private Limited	Rapid food testing kit/ media - Delvotest <sup>®</sup> Fast BT	Detect presence of Antibiotic Residues in Milk and Milk Products	Not Recommended. Does not cover the list of targeted antibiotic residues in milk.
16.	DSS Imagetech Private Limited	SEQLO System	RT-PCR Kit for milk species identification and adulteration	Not Recommended. Applicant should carry out the validation etc according to Internationally accepted procedures for DNA based tests such as Codex CAC/GL 74-2010 and a Validation through a collaborative trial.
17.	Nissui Pharmaceuticals	Rapid food testing kit/media - Compact Dry ( <i>Salmonella</i> )	Enumeration of <i>Salmonella</i> - Food products testing, Specifically for rapid microbial testing of raw and finished food, water	Not recommended. There are no approvals or validation of this compact media.
18.	Nissui Pharmaceuticals	Rapid food testing kit/media - Compact Dry ( <i>Vibrio parahaemolyticus</i> )	Enumeration of <i>Vibrio parahaemolyticus</i> - Food products testing, Specifically for rapid microbial testing of raw and finished food, water	Not recommended. There are no documents for approvals and validation of this rapid kit.
19.	Biomerieux S.A	Rapid Equipment - Bact/Alert 3D	Automated system for detection of anaerobic organisms in food matrices	Not Recommended. The specified equipment and associated test procedures are not validated. This system cannot be used for official control or regulatory testing purposes.
20.	Biomerieux S.A	Rapid Equipment - D-Count	Automated system for rapid enumeration & commercial	Not Recommended. Validation documents are not provided for applicability in the

S. No.	Applicant	Rapid food testing kit/equipment/method	Proposed Regulatory Use- (specific product testing/analytical method)	Recommendation Status
			sterility testing in food matrices	required food matrix.
21.	Anchrom Enterprises (I) P. Ltd.	Rapid Method	HPTLC-MS method for Detection of synthetic drugs in botanicals as per US Pharmacopoeia Chapter 2251 method	Not Recommended as rapid method. There is no proof that this technology is effective in food matrices as no validation data has been submitted.
22.	Anchrom Enterprises (I) P. Ltd.	Rapid Method	HP-TLC Fingerprint identification of materials botanical origin, based on US Pharmacopoeia Chapter 203 method	Not Recommended as rapid method. There is no proof that this technology is effective in food matrices as no validation data has been submitted.
23.	Anchrom Enterprises (I) P. Ltd.	Rapid Method	HP-TLC Fingerprint identification of vegetable oils, as per US Pharmacopoeia Chapter 202 method	Not Recommended as rapid method. There is no proof that this technology is effective in food matrices as no validation data has been submitted.
24.	Randox Laboratories (India) Pvt. Ltd.	Rapid Kit - Infiniplex Array Kit (IPM)	Testing of Antibiotic residue of 44 groups, Aflatoxin M1 and Melamine in Milk samples with a single kit	Not Recommended. This requires sophisticated instrument, trained manpower, high cost of testing, time intensive procedures. This may be suitable for a laboratory but not as a rapid test.

===000===