GUJARAT AUTHORITY FOR ADVANCE RULING GOODS AND SERVICES TAX D/5, RAJYA KAR BHAVAN, ASHRAM ROAD, AHMEDABAD – 380 009.	

ADVANCE RULING NO. GUJ/GAAR/R/2025/28

(IN APPLICATION NO. Advance Ruling/SGST&CGST/2024/AR/14)

Date:22/08/2025

Name and address of the applicant	:	M/s. Beacon Diagnostics P Ltd New GIDC Estate, Kabilpore, Navsari, Gujarat- 396 424
GSTIN of the applicant	:	24AABCB2080R1ZJ
Jurisdiction Office	:	Office of the Assistant Commissioner of State Tax, Unit-72, Range- 18, Division-8, Navsari.
Date of application	:	31.05.2024
Clause(s) of Section 97(2) of CGST / GGST Act, 2017, under which the question(s) raised.	:	(a)
Date of Personal Hearing	:	29.07.2025,23.1.2025 and 22.5.2025
Present for the applicant	:	Shri Moiz Ezzi, CA

Brief facts:

M/s. Beacon Diagnostics P Ltd, New GIDC Estate, Kabilpore, Navsari, Gujarat- 396 424 [for short –'applicant'] having their corporate office at 424, New G.I.D.C Estate Kabilpore, Navsari, Gujarat, India, 396424 is *inter alia* engaged in the business of supply of various diagnostics re-agents. The applicant is registered with the department and their registration no. is 24AABCB2080R1ZJ.

2. Briefly, the details as submitted by the applicant are as under:

- that they seek a ruling on the HSN and GST rate for their three products viz (i) CRP Turbilatex test kit, (ii) HbA1c test kit, and (iii) Microalbumin Turbilatex test kit;
- that the competing entries as far as classification of the above kits are concerned is
  - HSN 3002 at entry No. 125 of List 1 of serial No. 180 under Schedule-1 of the notification No. 1/2017-CT(R) dated 28.6.2017 as "Agglutinating Sera"; or
  - HSN 3822 at serial No 80 under Schedule -II of the notification No. 1/2017-CT(R) dated 28-06-2017 as "diagnostic kits and reagents";
- **CRP test kit** is used for the purpose of quantitative determination of C-Reactive Protein (CRP) in human serum; that this kit is based on agglutination principle between latex particles coated with specific anti-human CRP to determine CRP in the sample; that the kit is meant for *in vitro* diagnostic use;
- **HbA1c test kit** is used for the quantitative determination of hemoglobin Ale (HbA1c) in human blood; that the kit is based on agglutination principle by antigen-antibody interaction to directly determine the HbA1c concentration in the whole blood; that the kit is meant for in vitro diagnostic use.

- **Microalbumin turbilatex** is a quantitative turbidimetric test for the measurement of microalbumin (μALB) in human urine; that the kit is based on agglutination principle where latex particles coated with specific antibodies against human albumin agglutinate when mixed with samples containing μALB; that agglutination causes an absorbance change that can be quantified.

The applicant has further stated that the three kits are nothing but antisera in the form of kit; that they are used for diagnostic purposes ie detection of quantitative determination of CRP in human serum, HbA1c in human blood and Microalbumin in human urine, respectively, and are prescribed for invitro diagnostic use only.

3. The applicant has further contended as follows *viz*

- that serial No. 125 of list I of serial no. 180 of schedule I of notification No. 1/2017-CT(R) dated 28.6.2017, does not mention the word diagnostic kit but covers "Agglutinating sera" which is an individual product and not as a diagnostic Kit which works on the principle of the Agglutinating sera;
- that non-mention of the word "Kit" after the word "Agglutinating sera" under Sr. No. 125 of List 1 of Schedule 1 **is irrelevant**;
- that "Antisera" under CSH 3002 covers diagnostic kits which works on the principle of antisera/agglutinting sera;
- that the Courts have consistently held that 'antisera' under CSH 3002 would cover kits which are derived from antisera;
- that in this connection they would like to rely on the case of Span Diagnostics Ltd[1] and J Mitra & Co[2];
- kits under consideration consist of mainly three components of which one of the components is based on antisera, whereas another component is chemical/calibrator;
- that the essential component of the **CRP Test Kit** is R2 [i.e., latex particles coated with specific anti human CRP (i.e., antisera)]; that without R2, CRP in sample/specimen cannot take place & quantitative determination of CRP in the human serum cannot be determined; that around 70-80% of the total volume of the CRP Test Kit is attributable to component R2 which is the 'principal supply';
- that the essential component of **HbA1C test kit** is component R2 [i.e Mouse anti-human HbAlc monoclonal antibody & goat anti-mouse 1gG polyclonal antibody (i.e., antisera)]; that without R2, reaction with HbAlc in the sample/ specimen could not take place; that quantitative determination of HbAlc in human blood cannot be determined; that around 65% of the total volume of the HbA1c Test kit is attributable to component R2 & thus a 'principal supply';
- the essential component in **Microalbumin Turbilatex** is latex particles coated with specific antibodies anti human albumin (i.e. antisera) without which reaction with Microalbumin in the sample/ specimen could not take place and hence, quantitative determination of microalbumin in the human urine could not be determined; that 70%-75% of the total volume of the Kit is attributable to component R2, thus, it is evident that R2 is the 'principal supply';
- that tax liability applicable to the principal supply would apply to the entire composite supply;
- that only those diagnostic/laboratory reagents which cannot appropriately be classified under CSH 3002 will fall under CSH 3822;
- that they would like to rely on the case of Inter Care Ltd.[3]

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[1] 2007 (211) ELT 521 (SC)
[2] 2002 (140) ELT 524 (T)
[3] 1997 (89) ELT 545 (T

- the impugned product CRP Test kit is based on mice anti- CRP antibody/mice antisera & thus covered under chapter 3002 as it is specifically excluded from chapter 3822; that chapter heading 3002 is the default entry for diagnostic kits;
- that they would like to rely on the case of Span Diagnostic Ltd. [4] and Advance ruling in the case of Accurex Biomedical P Ltd.

6. In view of the foregoing, the applicant has sought a ruling on the below mentioned question *viz*:

> *"The classification in the tariff ie harmonized system of nomenclature (HSN) & GST rate has been sought viz*
> *a. CTP Turbilatex test kit*
> *b. HbA1c test kit*
> *c. Microalbumin Turbilatex test kit."*

7. Personal hearing was granted on 23.01.2025, wherein Shri Hitesh Kalsaria, Dy General Manager-Commercial, Shri Hardik Vashi, Technical Manager, Shri Pravin R Ahir, Manager and Shri Moiz Ezzi, CA appeared on behalf of the applicant and reiterated the submission already made in the application. They also submitted certificate in respect of the three test kits issued by Dr. Pradip Desai, MD (Path), Desai Clinical Laboratory. A further hearing was held on 22.5.2025.

7.1 In pursuance to the change in Member (State), a fresh personal hearing was held on 29.7.2025, wherein Shri Moiz Ezzi, CA appeared on behalf of the appellant and reiterated the submissions made in the application.

Discussion and findings

8. At the outset, we would like to state that the provisions of both the CGST Act and the GGST Act are the same except for certain provisions. Therefore, unless a mention is specifically made to such dissimilar provisions, a reference to the CGST Act would also mean a reference to the same provisions under the GGST Act.

9. We have considered the submissions made by the applicant in their application for advance ruling as well as the submissions made during the course of personal hearing. We have also considered the issue involved, the relevant facts & the applicant's submission/interpretation of law in respect of question on which the advance ruling is sought.

[4] 2007 (211) ELT 521 (SC

10. The question to be decided in the present application is the classification & GST rate applicable to the three test kits. The applicant claims that the test kits viz

a. *CTP Turbilatex test kit*
b. *HbA1c test kit*
c. *Microalbumin Turbilatex test kit."*

merit classification under HSN 3002 and not under HSN 3822.

11. Before dwelling on to the question on which the applicant has sought a ruling, it would be prudent to reproduce the relevant tariff headings, explanatory notes, exemption notification, for ease of understanding viz [relevant extracts]

CUSTOMS TARIFF OF INDIA

➢ Chapter 30

Pharmaceutical Products

Notes :

1. This Chapter does not cover:

(a) to (g) ..;

(h) blood albumin not prepared for therapeutic or prophylactic uses (heading 3502); or

(ij) diagnostic reagents of heading 3822.

2. For the purposes of heading 3002, the expression —immunological products‖ appliesto peptides and proteins (other than goods of heading 2937) which are directly involved in the regulation of immunological processes, such as monoclonal antibodies (MAB), antibody fragments, antibody conjugates and antibody fragment conjugates, interleukins, interferons (IFN), chemokines and certain tumor necrosis factors (TNF), growth factors(GF), hematopoietins and colony stimulating factors(CSF).;

➢ CTH 3002

3002		**HUMAN BLOOD; ANIMAL BLOOD PREPARED FORTHERAPEUTIC, PROPHYLACTIC OR DIAGNOSTIC USES; ANTISERA, OTHER BLOOD FRACTIONS AND IMMUNOLOGICAL PRODUCTS, WHETHER OR NOT MODIFIED OR OBTAINED BY MEANS OF BIOTECHNOLOGICAL PROCESSES; VACCINES,TOXINS, CULTURES OF MICRO-ORGANISMS (EXCLUDING YEASTS) AND OTHER SIMILAR PRODUCTS; CELL CULTURES, WHETHER OR NOT MODIFIED**	
	-	*Antisera, other blood fractions and products, immunological whether or not modified or obtained by biotechnologicalprocesses:*	
3002 12	--	Antisera and other blood fractions:	
3002 12 10	---	For diphtheria	kg.
3002 12 20	---	For tetanus	kg.
3002 12 30	---	For rabies	kg.
3002 12 40	---	For snake venom	kg.
3002 12 90	---	Other	kg.
3002 13 00	--	Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale	kg.
3002 14 00	--	Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale	kg.

3002 15 00	--	Immunological products, put up in measured doses or in forms or packings for retail sale	kg.
	-	*Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products:*	
3002 41	--	*Vaccines for human medicine:*	
	---	*Single vaccines for:*	
3002 41 11	----	Cholera and typhoid	kg.
3002 41 12	----	Hepatitis	kg.
3002 41 13	----	Tetanus	kg.
3002 41 14	----	Polio	kg.
3002 41 15	----	Tuberculosis	kg.
3002 41 16	----	Rabies	kg.
3002 41 17	----	Japanese encephalitis	kg.
3002 41 18	----	Whopping cough (pertusis)	kg.
3002 41 19	----	Other	kg.
	---	*Mixed vaccines for:*	
3002 41 21	----	Diphtheria, pertusis and tetanus (DPT)	kg.
3002 41 22	----	Diphtheria and tetanus (DT)	kg.
3002 41 23	----	Measles, mumps and rubella (MMR)	kg.
3002 41 24	----	Typhoid-paratyphoid (TAB)	kg.
3002 41 25	----	Typhoid- paratyphoid-cholera (TABC)	kg.
3002 41 29	----	Other	kg.
3002 42 00	--	Vaccines for veterinary medicine	kg.
3002 49	--	*Other*	
3002 49 10	---	Cultures of micro-organisms (excluding yeast)	kg.
3002 49 20	---	Toxins	kg.
3002 49 90	---	Other	kg.
	-	*Cell cultures, whether or not modified:*	
3002 51 00	--	Cell therapy products	kg.
3002 59 00	--	Other	kg.
3002 90	-	Other:	kg.
3002 90 10	---	Human blood	kg.
3002 90 20	---	Animal blood prepared for therapeutic, prophylactic or diagnostic uses	kg.
3002 90 90	---	Other	kg.

➢ HSN explanatory notes

30.02 - Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products (+).

- Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes :

3002.11 - - Malaria diagnostic test kits

3002.12 - - Antisera and other blood fractions

3002.13 - - Immunological products, unmixed, not put up in measured doses or in forms or packings for retail sale

3002.14 - - Immunological products, mixed, not put up in measured doses or in forms or packings for retail sale

3002.15 - - Immunological products, put up in measured doses or in forms or packings for retail sale

3002.19 - - Other

3002.20 - Vaccines for human medicine

3002.30 - Vaccines for veterinary medicine

3002.90 - Other

This heading covers :

(A) **Human blood** (e.g., human blood in sealed ampoules).

(B) **Animal blood prepared for therapeutic, prophylactic or diagnostic uses.**

Animal blood not prepared for such uses falls in **heading 05.11**.

(C) **Antisera, other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes.**

These products include :

(i) **Antisera and other blood fractions, whether or not modified or obtained by means of biotechnological processes.**

Sera are the fluid fractions separated from blood after clotting.

The heading covers, *inter alia*, the following products derived from blood (including vascular endothelial cells) : "normal" sera, human normal immunoglobulin, blood fractions and truncated variants (parts) thereof with enzymatic properties/activity, plasma, thrombin, fibrinogen, fibrin and other blood coagulation factors, thrombomodulin, blood globulins, serum globulins, and haemoglobin. This group also includes modified thrombomodulins and modified haemoglobins obtained by means of biotechnological processes, e.g., sothrombomodulin alfa (INN) and thrombomodulin alfa (INN), as well as cross-linked haemoglobins such as hemoglobin crosfumaril (INN), hemoglobin glutamer (INN) and hemoglobin raffimer (INN).

The heading further includes blood albumin (e.g., human albumin obtained by fractionating the plasma of whole human blood), prepared for therapeutic or prophylactic uses.

Antisera are obtained from the blood of humans or of animals which are immune or have been immunised against diseases or ailments, whether these are caused by pathogenic bacteria and viruses, toxins or allergic phenomena, etc. Antisera are used against diphtheria, dysentery, gangrene, meningitis, pneumonia, tetanus, staphylococcal or streptococcal infections, snake bite, vegetable poisoning, allergic diseases, etc. Antisera are also used for diagnostic purposes, including in vitro tests. Specific immunoglobulins are purified preparations of antisera.

The heading **does not cover** blood albumin not prepared for therapeutic or prophylactic uses (**heading 35.02**) or globulins (other than blood globulins and serum globulins) (**heading 35.04**). The heading also **excludes** medicaments which are not separated from the blood but which in some countries are described as "sera" or "artificial sera"; they include isotonic solutions based on sodium chloride or other chemicals and suspensions of pollen which are used against allergic diseases.

(2) **Immunological products, whether or not modified or obtained by means of biotechnological processes.**

Products used for diagnostic or therapeutic purposes and for immunological tests are to be regarded as falling within this product group. They can be defined as follows :

(a) **Monoclonal antibodies (MAB)** - specific immunoglobulins from selected and cloned hybridoma cells cultured in a culture medium or ascites.

(b) **Antibody fragments** – active parts of an antibody protein obtained by means of e. g., specific enzymatic splitting. This group includes inter alia single-chain (scFv) antibodies.

(c) **Antibody conjugates and antibody fragment conjugates** – conjugates which contain at least one antibody or an antibody fragment. The simplest types are a combination of the following :

(i) antibody – antibody;
(ii) antibody fragment – antibody fragment;
(iii) antibody – antibody fragment;
(iv) antibody – other substance;
(v) antibody fragment – other substance.

Conjugates of types (iv) and (v) include, for example, enzymes (e.g., alkaline phosphatase, peroxidase or betagalactosidase) or dyes (fluorescin) covalently bound to the protein structure, which are used for straightforward detection reactions.

This heading also covers interleukins, interferons (IFN), chemokines and certain tumor necrosis factors (TNF), growth factors (GF), hematopoietins and colony stimulating factors (CSF).

(D) **Vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.**

These products include :

(E) **Diagnostic kits.**

Diagnostic kits are classified here when the essential character of the kit is given by any of the products of this heading. Common reactions occurring in the use of such kits include agglutination, precipitation, neutralization, binding of complement, haemagglutination, enzyme-linked immunosorbent assay (ELISA), etc. Malaria diagnostic kits based on monoclonal antibodies to pLDH (plasmodium lactate dehydrogenase) are for instance classified here. The essential character is given by that single component which governs to the greatest extent the specificity of the test procedure.

The products of this heading remain classified here whether or not in measured doses or put up for retail sale and whether in bulk or in small packings.

Subheading 3002.13

The unmixed immunological products of subheading 3002.13 may contain impurities. The term "impurities" applies exclusively to substances whose presence in the products results solely and directly from the manufacturing process (including purification). These substances may result from any of the factors involved in the process and are principally the following :

(a) Unconverted starting materials.

(b) Impurities present in the starting materials.

(c) Reagents used in the manufacturing process (including purification).

(d) By-products.

➢ CHAPTER 38

Miscellaneous chemical products

2. (A) For the purpose of heading 3822, the expression —certified reference materials means reference materials which are accompanied by a certificate which indicates the values of the certified properties, the methods used to determine these values and the degree of certainty associated with each value and which are suitable for analytical, calibrating or referencing purposes.

(B) With the exception of the products of Chapter 28 or 29, for the classification of certified reference materials, heading 3822 shall take precedence over any other heading in the Schedule.

➢ CTH 3822

3822		**DIAGNOSTIC OR LABORATORY REAGENTS ON A BACKING, PREPARED DIAGNOSTIC OR LABORATORY REAGENTS WHETHER OR NOT ON A BACKING, WHETHER OR NOT PUT UP IN THE FORM OF KITS, OTHER THAN THOSE OF HEADING 3006; CERTIFIED REFERENCE MATERIALS**	
		Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits:	
3822 11 00	--	For malaria	kg.
3822 12 00	--	For Zika and other diseases transmitted by mosquitoes of the genus Aedes	kg.
3822 13 00	--	For blood-grouping	kg.
3822 19	--	Other:	
3822 19 10	---	Pregnancy test kit	kg.
3822 19 90	---	Other	kg.
3822 90	-	*Other:*	
3822 90 10	---	Certified reference materials	kg.
3822 90 90	---	Other	kg.

➢ HSN explanatory notes

38.22 - Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 30.02 or 30.06; certified reference materials.

This heading covers **diagnostic or laboratory reagents on a backing, prepared diagnostic** or **laboratory reagents, other than** diagnostic reagents of **heading 30.02** or diagnostic reagents designed to be administered to the patient and blood grouping reagents of **heading 30.06**. It also covers **certified reference materials**. Diagnostic reagents are used in the evaluation of physical, biophysical or biochemical processes and states in animals and humans; their function is based upon a measurable or observable change in the biological or chemical substances constituting the reagent. Prepared diagnostic reagents of this heading may be similar in function to those designed to be administered to patients (subheading 3006.30), with the exception that they are used for *in vitro*, rather than for *in vivo*, applications. Prepared laboratory reagents include not only diagnostic reagents, but also other analytical reagents used for purposes other than detection or diagnosis. Prepared diagnostic and laboratory reagents may be used in medical, veterinary, scientific or industrial laboratories, in hospitals, in industry, in the field or, in some cases, in the home.

Reagents of this heading are either on a backing or in the form of preparations and thus comprise more than a single constituent. For example, they may consist of admixtures of two or more reagents or of single reagents dissolved in solvents other than water. They may also be in the form of paper, plastics or other materials (used as backings or support), impregnated or coated with one or more diagnostic or laboratory reagents, such as litmus, pH or pole-finding papers or pre-coated immuno-assay plates. Reagents of this heading may also be put up in the form of kits, consisting of several components, even if one or more components are separate chemically defined compounds of Chapter 28 or Chapter 29, synthetic colouring matter of heading 32.04 or any other substance which, when presented separately, would be classifiable under another heading. Examples of such kits are those for testing glucose in blood, ketones in urine, etc., and those based on enzymes. However, diagnostic kits having the essential character of products of **heading 30.02** or **30.06** (e.g., those based on monoclonal or polyclonal antibodies) are **excluded**.

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for *in vitro* or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

With the exception of the products of **Chapter 28** or **29**, for the classification of certified reference materials, heading 38.22 shall take precedence over any other heading in the Nomenclature.

The certified reference materials of this heading are reference materials prepared for the calibration of an apparatus, the assessment of a measurement method or the assignment of values to a material. These reference materials may consist of the following :

(a) Substrate materials containing added analytes, the concentration of which has been accurately determined;

(b) Unmixed materials, the concentration of certain components of which has been accurately determined (e.g., the protein and fat content of milk powder);

(c) Materials, whether natural or synthetic, certain properties of which have been accurately determined (e.g., tensile strength, specific gravity).

These reference materials must be accompanied by a certificate which indicates the values of the certified properties, the methods used to determine the values and the degree of certainty associated with each value, and the certifying authority.

The heading also excludes the following reagents, whether or not put up in forms for use as diagnostic or laboratory reagents :

(a) Goods of **headings 28.43 to 28.46 and 28.52** (see Note 1 to Section VI);

(b) Products covered by Note 1 to Chapter 28 or Note 1 to Chapter 29;

(c) Colouring matter of **heading 32.04**, including preparations mentioned in Note 3 to Chapter 32;

(d) Prepared culture media for the development or maintenance of micro-organisms (including viruses and the like) or of plant, human or animal cells (**heading 38.21**).

- **Notification No. 1/2017-CT (R) dated 28.6.2017, as amended**

Schedule I – 2.5%

S. No.	Chapter/ Heading/ Sub-heading/ Tariff Item	Description of goods
180	[5]30 or any chapter	Drugs or medicines including their salts and esters and diagnostic test kits, specified in List I appended to this Schedule.

List I (See S. No. 180 of Schedule I)

(125) Agglutinating Sera

Schedule II – 6%

S. No.	Chapter/ Heading/ Sub-heading/ Tariff Item	Description of goods
80	3822	All diagnostic kits and reagents.

12. As the details of the kits have already been listed above it is not being repeated for the sake of brevity. However, the applicant has stated that the primary ingredient of the test kit is anti sera, in respect of all the three kits.

13. Chapter 38 deals with miscellaneous chemical products. HSN 3822 deals with "Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, whether or not put up in the form of kits, other than those of heading 3006; certified reference materials".

[5] corrected by M.F.(D.R) corrigendum F. No. 354/117/2017-TRU dtd 30.6.2017.

The explanatory notes of HSN 38.22 though reproduced supra, we find that it broadly states as under:

- HSN 3822 covers diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents, **other than diagnostic reagents of heading 30.02** or diagnostic reagents designed to be administered to the patient and. blood grouping reagents of heading 30.06;
- Diagnostic reagents are used in the evaluation of physical, biophysical or biochemical processes and states in animals and humans; their function IS based upon a measurable or observable change in the biological or chemical substances constituting the reagent;
- Prepared diagnostic & laboratory reagents of this heading may be [a] similar in function to those designed to be admmistered to patients (subheading 3006.30), with the exception that they are used for in vitro, rather than for in vivo, applications; [b] include not only diagnostic reagents, but also other analytical reagents used for pmposes other than detection or diagnosis; and [c] may be used in medical, veterinary, scientific or industrial laboratories, in hospitals, in industry, in the field or, in some cases, in the home;
- Reagents of this heading are either on a backing or in the form of preparations and thus comprise more than a single constituent. For e.g. they may consist of admixtures of two or more reagents or of single reagents dissolved in solvents other than water; that they may also be in the form of paper, plastics or other materials (used as backings or support), impregnated or coated with one or more diagnostic or laboratory reagents, such as litmus, pH or pole-finding papers or pre-coated innnuno-assay plates;
- **However, diagnostic kits having the essential character of products of heading 30.02 or 30.06 (e.g., those based on monoclonal or polyclonal antibodies) are excluded**.

14. The reason for discussing the explanatory notes of HSN 3822 firstly was the recent change in HSN Tariff with effect from 1-1-2022, wherein Chapter Note 1 (ij) was inserted in Chapter 30 which specifies that if it is a diagnostic reagents of Heading 3822 then the same would not be covered under Chapter 30. Therefore, what needs to be determined first is whether the three diagnostic kits would fall under Chapter Heading 3822.

15. We have already stated supra, that the applicant has stated that the primary ingredient of the test kit is *anti sera*. The explanatory notes in chapter 3002 describes antisera as "***Antisera*** *are obtained from the blood of humans or of animals which are immune or have been immunized against diseases or ailments, whether these are caused by pathologic bacteria and viruses, toxins or allergic phenomena, etc. Antisera are used against diphtheria, dysentery, gangrene, meningitis, pneumonia, tetanus, staphylococcal or streptococcal infections, snake bite, vegetable poisoning, allergic diseases, etc. Antisera are also used for diagnostic purposes, including in vitro tests. Specific immunoglobulins are purified preparations of antisera*". The applicant has also submitted Annexure-1 in respect of their products, which emphasize the fact that the primary ingredient of the test kit is anti sera, viz

> **[a] CRP LATEX** is manufactured by using AGGLUTINETING SERA namely specific antihuman CRP for the detection of CRP based on the principal of AGGLUTI NATION as an antigen antibody reaction

[b]CRP (C-Reactive Protein) Turbilatex is a quantitative turbidimetric test for the measurement of CReactive Protein (CRP) in human serum or plasma. Latex partial coated with specific anti-human CRP are agglutinated when mixed with samples coating CRP.

[c] **HbAlc Latex** is manufactured by using agglutinating sera namely anti human HbAlc monoclonal antibody and anti HbAlc mouse anti human sera.

[d] **HbAlc-Turbilatex** ex is manufacture by using agglutinating sera namely anti human HbAlc monoclonal antibody and anti HbAIC mouse anti human sera

[e] **Microalbumin Turbilatex** is a turbidimetric test where latex particles coated with specific antibodies against human albumin agglutinate when mixed with samples containing pALB. This agglutination causes an absorbance change that can be quantified

We find that the applicant in his submission dated 31.5.2024 in paragraph 5,6 and 7 under contention 2 has stated that anti sera constitutes 70-80% of the total volume in CRP Test kit, 65% of the total volume in HbA1c test kit and 70-75% of the total volume in Microalbumin Turbilatex Test Kit.

16. The classification of the said product, we find, is no longer *res integra* having already been decided by the Hon'ble Supreme Court in the case of Span Diagnostics Ltd.[6]. The relevant extract is reproduced for ease of reference viz

> *21. As stated above, Chapter Heading 30.02 refers to antisera and other blood fractions. According to the Explanatory Note in HSN (Seventh Edition), antisera is obtained from the blood of humans or animals which are immune against diseases. Antisera is used for diagnostic purposes, including in-vitro tests. There is nothing like crude antisera and refined antisera. In the present case, even according to the Department, PTK is an antisera, however, according to the Department, PTK is a refined antisera. As stated, antisera falls under Chapter Heading 30.02. In the circumstances, "antisera" is covered by Chapter Heading 30.02 and since it is covered by that Heading, Chapter Heading 38.22 will not apply. If one reads Chapter Heading 38.22, it becomes clear that there could be diagnostic or laboratory reagents which could fall under Chapter Heading 30.02 and also under Chapter Heading 38.22. However, if a diagnostic or laboratory reagent like antisera falls under Chapter Heading 30.02 then it stands excluded from Chapter Heading 38.22.*

[6] 2007 (211) E.L.T. 521 (S.C.)

35. *Now, coming to Item Nos. 1 to 15 of Annexure B, we quote herein below the said items which read as under :*

"ANNEXURE - 'B'

Name of the products which will fall under chapter sub-heading 3822

"ANNEXURE - 'B'

Name of the products which will fall under chapter sub-heading 3822

Sr. No.	Code No.	Item	
1.	17401A	Anti Sheep Hemolysin	5 ML
2.	19404	Chem. Control (Assayed)	5x3 ML
3.	19404A	Chem. Control (Unassayed)	5x3 ML
4.	17405	Fraund's Adjuvant (Com)	10 ML
5.	17406	Guinea pig (Complement)	5x1 ML
6.	19408	Kahn VDRL + Va control	5 ML
7.	19409	Kahn VDRL - Va control	5 ML
8.	19444	Chem. Control Assayed Normal	5x3 ML
9.	19444A	Chem. Control Assayed Abnormal	5x3 ML
10.	25907	R.A. Test (Latax Test)	
11.	25907A	R.A. Test (Latax Test)	
12.	25934	C.R.P. (Latax Test)	
13.	25947	ASO (Latax Test)	
14.	25946B	Austragen (Latax Test)	
15.	25946C	Austracen (Latax Test)	

36. *According to the assessee, the above 15 items fall under Chapter Heading 30.02 as they are "blood fractions". This is not disputed by the Department. However, according to the Department, since Item Nos. 1 to 15 are manufactured by coating latex particles with protein, they fall under Chapter Heading 38.22 of CETA. However, according to the Tribunal, the said items fall under Chapter Heading 30.05 of CETA. At this stage we may note that according to the Department, the said 15 items came under Chapter Heading 38.22 whereas, according to the assessee, they came under Chapter Heading 30.02. The only question before the Tribunal was whether it came under Chapter Heading 38.22 or whether it came under Chapter Heading 30.02. In M/s. Mitra's case (which we have decided hereinabove vide C.A.No. 5322 of 2002), we have taken the view that "blood fractions" fall under Chapter Heading 30.02. Chapter Heading 30.02 refers to "blood fractions". Merely because the medium used is latex (rubber) or paper, will not bring the items under Chapter Heading 38.22. Once an item is a "Blood Fraction" it falls under Chapter Heading 30.02. The medium is irrelevant. The medium could be paper or rubber. The configuration of the product and the function are important. In our opinion, Item Nos. 1 to 15 are "Blood Fractions". They are "Blood Fractions" even according to the Department.*

37. *In the circumstances, we classify Item Nos. 1 to 15 of Annexure B to the paper book under Chapter Heading 30.02 (CSH 3002.00).*

17. We therefore find that the product [ie the three kits] does not merit classification under HSN 3822 and as has been held by the Hon'ble Supreme Court would merit classification under 3002. In-fact even in the explanatory notes of HSN 3002, it states that the heading covers

(E) Diagnostic kits. Diagnostic kits are classified here when the essential character of the kit is given by any of the products of this heading. Common reactions occurring in the use of such kits include agglutination, precipitation, neutralization, binding of complement, haemagglutination, enzyme-linked immunosorbent assay (ELISA), etc. Malana diagnostic kits based on monoclonal antibodies to pLDH (plasmodium lactate dehydrogenase) are for instance classified here. The essential character is given by that single component which governs to the greatest extent the specificity of the test procedure. The products of this heading remain classified here whether or

not in measured doses or put up for retail sale and whether in bulk or in small packings.

18. We further find that our above findings is substantiated vide the Maharashtra Appellate Authority for Advance Ruling dated 30.9.2022 in the case of M/s. Accurex Biomedical P Ltd..

19. Having said so, we find that the applicant is liable to discharge GST at the rate of 5% under Schedule -I [Sr. No. 180].

20. In view of above, we rule as under:

RULING

The below mentioned three test kits *viz*

(i) CTP Turbilatex test kit
(ii) HbA1c test kit
(iii) Microalbumin Turbilatex test kit."

is classifiable under HSN 3002 & is leviable to GST at the rate of 5% in terms of serial no. 180 of notification No. 1/2017-CT (Rate) dated 28.6.2017, as amended.

(Sushma Vora)
Member (SGST)

(Vishal Malani)
Member (CGST)

Place: Ahmedabad
Date: 12.08.2025