THE MAHARASHTRA APPELLATE AUTHORITY FOR ADVANCE RULING FOR GOODS AND SERVICES TAX

(Constituted under Section 99 of the Maharashtra Goods and Services Tax Act, 2017)

ORDER NO. MAH/AAAR/AM-RM/ 12 /2022-23 **Date-** 30/09/2022

BEFORE THE BENCH OF

(1) Shri Ashok Kumar Mehta, MEMBER (Central Tax)

(2) Shri Rajeev Kumar Mital, MEMBER (State Tax)

Name and Address of the Appellant:	M/s. Accurex Biomedical Private Limited, 212 Udyog Mandir, Bhagoji Keer Marg, Mahim West, Mumbai-400 016.
GSTIN Number:	27AACCA3730G1Z1
Clause(s) of Section 97, under which the question(s) raised:	(a) Classification of any goods or services or both;
Date of Personal Hearing:	16.09.2022
Present for the Appellant:	(i) Abhinav Thakur (ii) Hema Patel
Details of appeal:	Appeal No. MAH/GST-AAAR/05/2021-22 dated 10.11.2021 against Advance Ruling No. GST-ARA-98/2019-20/B-72 dated 11.10.2021.
Jurisdictional Officer:	Deputy Commissioner, MUM-VAT-E-624, LTU-2 Mumbai

(Proceedings under Section 101 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017)

1. At the outset, we would like to make it clear that the provisions of both the CGST Act and the MGST Act are the same except for certain provisions. Therefore, **unless a mention is made in respect of such dissimilar provisions,** a reference to the CGST Act would also mean a reference to the same provisions under the MGST Act.

2. The present appeal has been filed under Section 100 of the Central Goods and Services Tax Act, 2017 and the Maharashtra Goods and Services Tax Act, 2017 [**hereinafter referred to as "CGST Act" and "MGST Act"**] by M/s. Accurex Biomedical Private Limited, 212 Udyog Mandir, Bhagoji Keer Marg, Mahim West, Mumbai-400 016 (**"hereinafter referred to as "the Appellant"**) against the Advance Ruling No GST-ARA-98/2019-20/B-72 dated 11.10.2021.,

pronounced by the Maharashtra Authority for Advance Ruling (hereinafter referred to as **"MAAR"**).

BRIEF FACTS

3. M/s. Accurex Biomedical Private Limited having its corporate office at 212, Udyog Mandir, Bhagoji Keer Marg, Mahim West, Mumbai - 400016, is, *inter-alia,* engaged in the business of supply of various diagnostic reagents.The Appellant have obtained registration and holding valid registration certificate issued under CGST Act, 2017.

4. Out of the various range of products, the Appellant sought ruling in respect of the classification of the following two products:

(A) Turbilatex CRP Infinite

(B) HbAlc Infinite

In the above, the word "Infinite" is brand name of the Appellant.

5. **(A) Infinite Turbilatex CRP**

5.1 Infinite Turbilatex CRP (hereinafter referred to as "CRP Test Kit") is supplied by the Appellant under the brand name "Infinite". This product is meant for *in-vitro* diagnostic use only.

Use or Purpose

5.2 CRP Test Kit is used for the quantitative determination of C-Reactive Protein (CRP) in human serum for medical diagnosis of inflammation and infections.

5.3 CRP Test kit contains the following components:

Components	Description
R1	Buffer Reagent
R2	Latex Reagent
R3	Calibrator Lyoph Serum Vial

5.4 Principle on which the product is based.

(i) CRP Test Kit is based on agglutination principle between latex particles coated with specific anti-human CRP to determine CRP in the sample. **To a naked eye**, it is impossible to detect the process of agglutination. That is why, to facilitate easy detection of agglutination, "carriers" were chosen on which the specific antibodies could be coated.

(ii) R2 **contains** latex particles coated with specific anti human CRP which reacts with CRP in the sample resulting in agglutination. Agglutination causes change in absorbance, measured at 540 nm (530 - 550 nm) & is proportional to the concentration of CRP in the sample.

(iii) The affinity purified polyclonal antibodies are coated on **the** latex particles, these latex beads act as carrier for the spectrophotometric detection of antigen CRP in human serum/plasma via reaction with agglutination sera coated onto the latex reagent.

(iv) The essential component of the CRP Test Kit is R2 since it contains the antiserum. In fact, around 85% of the total cost of the CRP Test Kit is attributable to component R2.

5.5 Preparation of Working Solution.

(i) Swirl the latex vial gently before use and prepare working solution by mixing R1 and R2 in the ratio 9:1 as per the requirement.

(ii) Lyophilized calibrator should be reconstituted by adding 1.0 ml of distilled or deionized water. Dissolve the contents of the vial by swirling gently to avoid the formation of foam.

(iii)The Appellant **does not** supply directly mixed solution of R1 and R2 since mixed solution i.e., CRP in serum is stable for 7 days at 2 - 8° C and for 3 months at -20° C. Hence, the shelf life of the product reduces if the **Appellant supplies** mixed solution of R1 and R2 which is not commercially viable. Hence, the **Appellant supplies** R1 and R2 separately in the same kit.

6. **(B) Infinite HbAlc**

6.1 Infinite HbAlcis supplied by the Appellant under the brand name "Infinite" or "AutoPure". This product is meant for in-vitro diagnostic use only.

6.2 The appellant supplies the said product in 4 different sizes namely (i)Infinite HbAlc 80; (ii) Infinite HbAlc 22; (iii) Infinite HbAlc 20 and (iv) AutoPureHbAlc 44. All the 4 sizes of the products have the same basic design, performance characteristics, effectiveness and intended use. The principle **underlying** usage of all the aforesaid products is also same. Because of similarity in the characteristics and usage of the above-mentioned products, hereinafter, the said products are collectively referred to as "HbA1c Test Kit".

Use or Purpose

6.3 HbA1c Test Kit is used for the quantitative determination of hemoglobin A1c (HbA1c) in human blood and monitoring of glycemic control in diabetic patients.

6.4 HbA1c Test Kit contains the following components:

Components	Description
R1	Latex reagent
R2	Buffered antibody reagent
R3	Hemolysis Reagent
R4	Optional - Calibrator made from human blood

6.5 Principle on which the product is based.

(i) HbA1c Test Kit is based on agglutination principle by antigen-antibody interaction to directly determine the Hb1Ac concentration in the whole blood.

(ii) HbA1c assay is based on antigen-antibody interaction to directly determine the HbA1c concentration in whole blood. Total haemoglobin and HbA1c have the same unspecific absorption rate to latex particles. When mouse antihuman HbA1c monoclonal antibody is added, latex- HbA1c-mouse antihuman HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse IgG polyclonal antibody interacts with the monoclonal antibody. The amount of agglutination is proportional to the concentration of the HbA1c in the specimen.

(iii) The affinity purified monoclonal antibodies are coated on to latex particles, these latex beads act as carrier for the spectrophotometric detection of antigen HbA1c in human serum/plasma via reaction with agglutination sera coated onto the latex reagent.

(iv) The essential component of the HbA1c Test Kit is R2 since it contains antiserum. In fact, around 75% of the total cost of the HbA1c Test Kit is attributable to component R2.

6.6 Preparation of Working Solution.

(i) Dispense R3 into appropriately labeled tube. Add Hb1Ac in whole blood collected with EDTA which was collected as specimen. Mix well and allow to stand until lysis is evident.

(ii) Prepare working solution by mixing R1 and R2 in the ratio as per the requirement specified. Thereafter, conduct test on the specimen mixed with R3.

(iii) The **Appellant does not supply** directly mixed solution of R1 and R2 since mixed solution would be stable for 3 days only. Hence, the shelf life of the product reduces if the **Appellant supplies** mixed solution of R1 and R2 which is not commercially viable. Hence, the appellant supplies R1 and R2 separately in the same kit.

(iv) Calibrators is used to analyze patient samples in accordance with the instructions outlined in Accurex HbA1c Reagent package insert by generating a calibration curve. The

calibrators should be treated in the same manner as **patient's** specimens for the preparation of hemolysate. The values of calibrators are assigned by assaying against the material referenced to NGSP values.

Application for Advance Ruling

7. In the above background, the Appellant filed an application for Advance Ruling before the MAAR, seeking an advance ruling on the question whether CRP Test Kit & Hb1Ac Test Kit is classifiable:

(a) **Under HSN Code 30.02 at Entry No.125 of List 1 of Sr. No 180 under Schedule–I of the Notification No.1/2017-Central Tax (Rate), dated 28.6.2017 as "Agglutinating Sera"; or**

(b) **Under HSN Code 38.22 at Sr. No 80 under Schedule–II of the Notification No.1/2017-Central Tax (Rate), dated 28.6.2017 as "diagnostic kits and reagents".**

Advance Ruling passed by MAAR, Maharashtra

8. The MAAR held that CRP kit and Hb1Ac kit do not fall under HSN code 3002, whereas the same are covered by HSN Code 3822 based on the following observation:

(i) Entry No.125 of List 1 of Sr. No. 180 of Schedule I of Notification No.1/2017-Central Tax (Rate), dated 28.6.2017, mentions the word "Agglutinating Sera". The said Entry does not mention the word 'diagnostic kits'. Whereas, there are other entries in the same List 1 wherein there is a specific mention of diagnostic kit. Therefore, "Agglutinating Sera" listed under Sr. No. 125 of List 1 of Schedule I covers agglutinating sera as an individual product and not as a diagnostic kit which works on the principle of "Agglutinating Sera".

(ii) **It was the submission of the Appellant that** both CRP kit and Hb1Ac kit fall under HSN Code 30.02 since both products work on the principle of Agglutinating Sera. The Appellant have not substantiated their contention either with any detailed submissions on the matter or on the basis of actual evidence. The Appellant have not given any submission with respect to the component of the kits which governs to the greatest extent the specificity of the test procedure. Therefore, the subject product cannot be covered under Heading 30.02 of the GST Tariff as contented by the applicant.

(iii) The **Appellant's** contention that their competitors are clearing similar goods under HSN Code 30.02 is not tenable since there are many more players in the market who are also classifying these goods under HSN Code 38.22.

(iv) CRP Test Kits and Hb1Ac Test Kits are not agglutinating sera by themselves. Rather they are diagnostic kits which may work on the principle of 'agglutinating sera'. Therefore, both products under consideration fall under HSN Code 38.22at Sr. No 80 under Schedule–II of the Notification No.1/2017-Central Tax (Rate), dated 28.6.2017 as "diagnostic kits and reagents", attracting GST @ 12%.

(v) Reagents of heading 38.22 may be put up in the form of kits consisting of other components, even if one or more components, when presented separately, would be classifiable under another heading. Examples of such include kits used for testing glucose in blood, etc.

(vi) As per Sr. No. 7 of Notification No. 05/2021-Central Tax (Rate) dated 14.6.2021, the GST rate on certain products, including CRP (C-Reactive Protein), falling under Heading 38.22 has been reduced to 5%. This Notification was valid up to 30th September 2021. The above notification has been issued during the COVID-19 Pandemic situation in India vide which Government of India announced reduction in the GST rates on the specified items being used in Covid-19 relief and management till 30.9.2021. So, the rate of GST on CRP was reduced to 5% for that particular period only else the rate is higher at 12%.

9. Aggrieved by the MAAR's ruling dated 11.10.2021, the Appellant filed the present appeal, *inter alia*, on the following grounds, which are without prejudice to each other.

GROUNDS OF APPEAL

10. The products under consideration namely CRP Test Kit and Hb1Ac Test Kit, is correctly classifiable under Chapter Sub-Heading 3002 as "Agglutinating Sera" at Entry No.125 of List 1 of Sr. No 180 under Schedule–I of the Notification No.1/2017-Central Tax (Rate), dated 28.6.2017.

10.1 Heading Description of Chapter Sub-Heading ("CSH") 3002 and CSH 3822 read as under:

Heading Codes	Heading Description
3002	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and modified immunological products, whether or not obtained by means of biotechnological processes; vaccines, toxins, Cultures of micro-organisms (excluding yeasts) and similar products.
3822	Diagnostic or laboratory reagents on a backing, prepared diagnostic or Laboratory reagents whether or not on a backing, other than those of heading 3002 or 3006;

10.2 In view of above, it can be said that only those diagnostic/laboratory reagents (whether or not on a backing) which cannot appropriately be classified under CSH 3002 will fall under CSH 3822.Therefore, it is to be examined whether the CRP Test Kits and Hb1Ac Test Kits in the instant case can be appropriately classified under CSH 3002.As can be seen from above, CSH 3002 covers, *inter-alia*, 'antisera and other blood fractions whether or not modified or obtained by means of biotechnological processes'.

10.3 To analyse the CSH 3002, reliance is placed on the Explanatory Notes to the Harmonized Commodity Description and Coding system of CSH3002, wherein it has been explained as follows:

> *(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.*
>
> .....
>
> .....
>
> *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.*
>
> [Emphasis supplied]

10.4 HSN Explanatory Notes to CSH 3002 states that 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 pathogenic bacteria and viruses, toxins or allergic phenomena, etc. The antisera are, *inter-alia*, used for diagnostic purposes, including in vitro tests.

10.5 CRP Test Kit is in-turn used for the purpose of quantitative determination of C-Reactive Protein (CRP) in human serum for medical diagnosis of inflammation and infections. CRP Test Kit is based on agglutination principle between latex particles coated with specific anti-human CRP to determine CRP in the sample. CRP Test Kit is meant for in vitro diagnostic use.

10.6 HbA1c Test Kit is used for the quantitative determination of hemoglobin Alc (HbA1c) in human blood for medical diagnosis and monitoring of glycemic control in diabetic patients. HbA1c Test Kit is based on agglutination principle by antigen-antibody interaction to directly determine the Hb1Ac concentration in the whole blood.HbA1c Test Kit is meant for in vitro diagnostic use.

10.7 At this juncture, reference can also be made to HSN Explanatory Note (E) to CSH 3002 which read as under:

"(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, hem agglutination, enzyme-linked immunosorbent assay (ELISA), etc. Malaria diagnostic kits monoclonal antibodies to pLDI-1 (plasmodium lactate dehydmgenase) 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."

[Emphasis supplied]

10.8 In the present case, antibodies used in CRP Test Kit supplied by the Appellant have been derived from Latex particles coated with anti-CRP antibody /mice antisera which is classifiable under CSH 3002. The essential component of the CRP Test Kit is R2 i.e., latex particles coated with specific anti human CRP since without which reaction with CRP in the sample/ specimen could not take place and hence, quantitative determination of CRP in the human serum could not be determined. In fact, around 85% of the total cost of the CRP Test Kit is attributable to component R2. Thus, it is evident that the essential character of CRP Test Kit is given by 'antisera' which is classifiable under CTH 3002.

10.9 Further, antibodies used in Hb1Ac Test Kit supplied by the Appellant have been derived from Mouse anti-human HbA1c monoclonal antibody & Goat anti-mouse IgG polyclonal antibody which is classifiable under CSH 3002. The essential component of the HbA1c Test Kit is component R2, i.e., Mouse anti-human HbA1c monoclonal antibody & Goat anti-mouse IgG polyclonal antibody since without which reaction with Hb1Ac in the sample/ specimen could not

take place and hence, quantitative determination of HbA1c in human blood would not be determined. In fact, around 75% of the total cost of the HbA1c Test Kit is attributable to component R2. Thus, it is evident that the essential character of Hb1Ac Test Kit is given by 'antisera' which is classifiable under CSH 3002.

10.10 In view of the above, it can be said that the said kits are nothing but antisera in the form of kit. The same can be supported by the fact that the CRP Test Kit and Hb1Ac Test Kit are used for diagnostic purposes i.e., detection of quantitative determination of CRP in human serum and HbA1c in human blood, respectively, and are prescribed for in vitro diagnostic use only.

11. <u>Once the diagnostic/laboratory reagents found to be appropriately classifiable under CSH 3002, the same will *ipso facto* remain outside the coverage of the residuary CSH 3822.</u>

11.1 It can be said that only those diagnostic/laboratory reagents which cannot appropriately be classified under CSH 3002 will fall under CSH 3822.As discussed in the paras supra, the subject kits under consideration are appropriately classifiable under CSH 3002 and hence, the same will ipso facto remain outside the coverage of the residuary CSH 3822. This view can be substantiated by the judgment of the various courts in the decisions discussed *infra.*

11.2 In the case of **J. Mitra & Co. Ltd. Vs. CCE – 2002 (140) ELT 524 (T)**, the assessee was manufacturing Beta Visipreg, Visipreg Strip and Pregnancy Test Card. The nature and function of the products were discussed in Para 4.1 of the judgment, which is reproduced hereunder:

"The above products were cleared by the appellant as pregnancy test kits' (in short, PTK). PTK is a rapid sensitive and accurate immunoassay for the visual qualitative detection of Human Chorionic Gonadotropin (HCG)-in the urine of a pregnant lady as an indicator of pregnancy. Normally, a pregnant lady secretes HCG which is secreted through urine. To produce the antibody for HCG, which could ultimately be used as an indicator in the PTK, HCG, which is glycoprotein hormone is injected in measured doses in **<u>rabbits or</u>** <u>Goats.</u> Because of the immunological systems present in rabbits and goats, antibodies are produced in the blood of the rabbit or goat. After sufficient period of time, the antibody for HCG is extracted and is used in the PTKs. PTKs themselves may be of different varieties like in the form of liquid, in the form of strip of paper, in the form of antisera or anti body or anti HCG dispersed on membrane as coated, or in the form of test kit card where also antisera antibody for HCG is coated. The test line in the strip of paper or on the card is an antisera antibody for HCG. "

11.3 In the above case, the assessee was clearing the pregnancy test kits under CSH 3002, whereas the department contended that the same would fall under CSH 3822 as "diagnostic or laboratory

reagent". The Hon'ble Tribunal after analyzing the HSN Explanatory notes and the characteristics of the products in dispute, concluded that the said products are "antisera" which is covered by CSH 3002 and since it is covered by that Heading, CSH 3822 will not apply. The relevant para from the decision is extracted hereunder:

> *"4.4....*
>
> .....
>
> *The anti-HCG antibodies used in the PTKs were derived from goat antisera classifiable under Heading 30.02. It follows that the PTKs, which were prescribed only for in vitro test for pregnancy and were not designed to be administered to the patient, would fall, as 'diagnostic or laboratory reagents', under Heading 30.02, which Heading specifically covers antisera. Diagnostic or laboratory reagents of Chapter 30 have been excluded from the coverage of Heading 38.22, which reads as under:-*
>
> *38.22 3822.00 Diagnostic or laboratory reagents on a backing and prepared diagnostic or laboratory reagents whether or not on a backing, other than those of Chapter 30.*
>
> *"Visipreg Strip" and "Preg Test Card", being anti-HCG antibody (from antisera) dispersed on membrane, will fit in with the description "diagnostic or laboratory reagents on a backing" while "Beta Visipreg" can appropriately be described as "prepared diagnostic or laboratory reagents whether or not on a backing". Though these descriptions literally exist in Heading 38.22 only, products of either of these descriptions can possibly belong to Chapter 30 as well, which is obvious from the language of Heading 38.22 itself. Going by the terms of Heading 38.22, we find that only those diagnostic/laboratory reagents (whether or not on a backing) which cannot appropriately be classified under Heading 30.02can fall under Heading 38.22. The above three products having been found to be appropriately classifiable under Heading 30.02 in Chapter 30 will ipso facto remain outside the coverage of the residuary Heading 38.22. Interpretative Rule 3(c) has no application to such a situation in which one of two competing entries is residual to the other. The adjudicating authority's observations on this aspect are patently erroneous."*
>
> *[emphasis supplied]*

11.4 Similar dispute was decided by the Hon'ble Supreme Court in the case of **Span Diagnostics Ltd. Vs. CCE – 2007 (211) ELT 521 (SC)**. In this case, the Hon'ble Supreme Court held as under:

17. *The short question which needs to be decided in these civil appeals is : Whether Beta Visipreg, Visipreg Strip, Pregnancy Test Card fall as "antisera" under Chapter Heading 30.02 of CETA (according to the assessee) or whether it falls under Chapter Heading 38.22 of CETA as "diagnostic or laboratory reagent" (as contended by the Department).*

18. *The above three products were cleared by the assessee as Pregnancy Test Kits (PTK). According to the assessee the above three products are for the detection of HCG hormones in urine, as a test for pregnancy. The three products are meant for in-vitro diagnostic use only. According to the assessee, Chapter Heading 30.02 covers antisera of all forms.*

19. *On the other hand, it was argued on behalf of the Department that although PTK was an antisera, the above three products were classifiable as diagnostic or laboratory reagents under Chapter Heading 38.22 as they were used exclusively in laboratory for diagnostic purposes. According to the Adjudicating Authority, Chapter Heading 30.02 applied only to crude antisera and since the above three products were refined antisera, they did not fall under Chapter Heading 30.02.*

.....

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.*

[emphasis supplied]

11.5 Further, reliance is placed on the decision of the judgement of Hon'ble Tribunal in the case of **Inter Care Ltd. Vs. CC – 1997 (89) ELT 545 (T).** In this case, an 'agglutinating serum' imported under "Preg Colour" brand name was found to be pregnancy test kit based on antigen - antibody reaction (as in the instant case) and it was held to be classifiable under Customs Tariff sub-heading 3002.10 (antisera and other blood fractions).

12. <u>Non-mention of the word "kit" after the word "agglutinating sera" under Sr. No. 125 of List 1 to Schedule I is irrelevant. It is settled legal position that "antisera" under CSH 3002 covers diagnostic kits which works on the principle of antisera/ agglutinating sera.</u>

12.1 Sr. No. 180 of Schedule I – CGST rate 2.50% read as under:

Sr.	Chapter/Heading/Sub-	Description of Goods
180	30	Drugs or medicines including their salts and esters and diagnostic test kits, specified in List I appended to this

12.2 Sr. No.125 of List 1 appended to the Schedule I read as under:

Sr. No. (125) - Agglutinating Sera.

12.3 As discussed in detail supra, CSH 3002 refers to antisera. According to the Explanatory Note in HSN, 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. Further, as per HSN Explanatory Note (E) to CSH 3002 diagnostic kits are classified under CSH 3002 when the essential character of the kit is given by any of the products of CTH 3002. In the present case, CRP Test Kit and Hb1Ac Test Kit is nothing but antisera in the form of kit. Therefore, covered under CSH 3002.

12.4 The objection raised by the MAAR has been considered by various courts and it is consistently held that "antisera" under CSH 3002 would also cover kit which are derived from antisera. Reliance in this regard is placed on the decision of **Span Diagnostics Ltd. Vs. CCE – 2007 (211) ELT 521 (SC)**, wherein, in the context of another item of CSH 3002 i.e., "Blood Fraction", the Hon'ble Supreme Court at para 36 of the judgement held that "Once an item is a "blood fraction" it falls under Heading 30.02 of Central Excise Tariff & merely because medium used is latex (rubber) or paper, will not bring the items under Heading 38.22 ibid - Medium is irrelevant." The medium could be paper or rubber. Configuration of product and function are important for classification.

12.5 Further, the Hon'ble CESTAT in the case of **J. Mitra & Co. Ltd. Vs. CCE –2002 (140) ELT 524 (T)** after examining the HSN Explanatory Notes to Heading 30.02 held that the term antisera in

Heading 30.02 would also include purified/refined forms of the antiserum fraction of blood. Based on this observation, the Hon'ble Tribunal held that anti-HCG antibodies used in the Pregnancy Test Kits were derived from goat antisera classifiable under Heading 30.02.

13. **In any case, the kits under consideration supplied by the Appellant is a composite supply and hence, the same would be classifiable under CSH 3002.**

13.1 Kits under consideration consist of mainly three components. Out of the three components, one of the components is based on antisera, whereas other component is chemical/ calibrator.

13.2 Section 2(30) of the CGST Act defines 'composite supply' as under:

2(30) "composite supply" means a supply made by a taxable person to a recipient **consisting of two or more taxable supplies** of goods or services or both, or any combination thereof, **which are naturally bundled and supplied in conjunction with each other** in the **ordinary course of business**, one of which is a principal **supply**;

[emphasis supplied]

13.3 Thus, 'composite supply' means a supply of two or more taxable supplies of goods or services or both which are:

- naturally bundled; and
- supplied in conjunction with each other in the ordinary course of business and
- one of which is a principal supply.

13.4 Section 2(90) of the CGST Act defines 'principal supply' as under:

2(90) "principal supply" means the supply of goods or services which constitutes the **predominant element of a composite supply** and to which **any other supply forming part of that composite supply is ancillary.**

... **[emphasis supplied]**

13.5 'Principal supply' means supply of goods or service which is the predominant element of a composite supply to which the other supplies are only ancillary.

13.6 In the present case, the essential component of the CRP Test Kit is R2 i.e., latex particles coated with specific anti human CRP (i.e., antisera) since without which reaction with CRP in the sample/ specimen could not take place and hence, quantitative determination of CRP in the human serum could not be determined. In fact, around 85% of the total cost of the CRP Test Kit is attributable to component R2. Thus, it is evident that R2 is the predominant component of the CRP Test Kit and hence, component R2 would constitute as 'Principal supply'.

13.7 Further, the essential component of the HbA1c Test Kit is component R2 i.e., Mouse anti-human HbA1c monoclonal antibody & Goat anti-mouse IgG polyclonal antibody (i.e., antisera) since without which reaction with Hb1Ac in the sample/ specimen could not take place and hence, quantitative determination of HbA1c in human blood would not be determined. In fact, around 75% of the total cost of the HbA1c Test Kit is attributable to component R2. Thus, it is evident that R2 is the predominant component of the Hb1Ac Test Kit and hence, component R2 would constitute as 'Principal supply'.

13.8 As per Section 8 of the CGST Act, the composite supply will be treated as the supply of the principal supply. Therefore, tax liability applicable to the principal supply would apply to the entire composite supply.

13.9 In view of the above, supply of kits being composite supply, tax rate applicable to the principal supply i.e., component R2 would apply to the entire amount charged towards supply of kits under consideration.

13.10 In the present case, component R2 in both CRP Test Kit as well as Hb1Ac Test Kit is "antisera" which is covered under Entry No.125 of List 1 of Sr. No. 180 of Schedule I of Notification No.1/2017-Central Tax (Rate), dated 28.6.2017 chargeable to 5% rate of GST. Therefore, GST rate @ 5% applicable to component R2 would apply to the entire amount charged towards supply of kits under consideration.

14. <u>Reliance placed on Sr. No. 7 of Notification No. 05/2021-Central Tax (Rate) dated 14.6.2021 for deciding classification of the kits under CSH 3822, is absurd and perverse.</u>

14.1 As per MAAR, vide the said notification, the GST rate on certain products, including CRP (C-Reactive Protein), falling under Heading 38.22 has been reduced to 5%. This Notification was valid up to 30thSeptember 2021. The above notification has been issued during the COVID 19 Pandemic situation in India vide which Government of India announced reduction in the GST rates on the specified items being used in Covid-19 relief and management till 30.9.2021. As per MAAR, the rate of GST on CRP was reduced to 5% for that particular period only else the rate is higher at 12%.

<u>RESPONDENT'S SUBMISSIONS</u>

15. The Jurisdictional Officer vide their letter dated 26.11.2021 have made the following submissions:

a) that on comparison of similar products like CRP and HbA1c supplied by other registered persons, it appeared that few registered person have confusion over the rate of tax like Beacon diagnostic private limited and tulip diagnostics(p) limited, who levy GST at 5% on supply of CRP, otherwise levy 12% of GST on supply of CRP and HbA1c;

b) that HbA1c is haemoglobin A1c, and important diagnostic tool but not specified in list1 appended to the schedule I. It is not agglutinating sera. The Hba1c falls under the HSN code 3822.

c) that the CRP is a protein made reagent that does not fall under HSN code 3002 and is taxable @12% under GST.

d) the GST rate fixed on all diagnostic kits and reagents by GST council on 18th May, 2017 was 18%. However, GST council trimmed GST levied rate on all diagnostic kits and reagents to 12% as per GST council meet held on 11th June,2017.

e) Changes to GST rate of Goods as decided by the 16th GST council meeting (changes to GST rate-GST council meeting held on 11th June, 2017).

HSN Code	**Description of Goods**	**Old GST Rate (GST council held on 18th May, 2017)**	**New GST Rate (GST council held on 11th June, 2017)**
3822	All diagnostic kits and reagents	18%	12%

f) that the GST rate applicable on supply of HbA1c and CRP is @12% i.e. (6% CGST and 6% SGST).

Personal Hearing

16. The personal hearing in the matter was conducted on 16.09.2022 in virtual mode via Video Conferencing, which was attended by Mr. Abhinav Thakur and Ms. Hema Patel on behalf of the Appellant. Shri Thakur reiterated the earlier submissions made while filing the present appeal. He contended that the products under consideration namely CRP Test Kit and Hb1Ac Test Kit, are correctly classifiable under Chapter Sub-Heading 3002 attributable to the "Agglutinating

Sera" enumerated at Entry No.125 of List 1 of Sr. No 180 of Schedule–I to the Notification No.1/2017-Central Tax (Rate), dated 28.6.2017. In support of his contention, he referred to the Explanatory Notes in which the meaning and scope of *Antisera have been dealt with. He further referred to the Explanatory Note (E) to Chapter Heading 30.02 which states that* Diagnostic kits are classified here when the essential character of the kit is given by any of the products of this heading. The said explanatory note also states that the essential character is given by that single component which governs, to the greatest extent, the specificity of the test procedure. He also relied upon the Hon'ble Supreme Court case of **Span Diagnostics Ltd. Vs. CCE – 2007 (211) ELT 521 (SC)** along with some other cases.

Additional Submissions dated 22.09.2022

17. The Appellant also filed an additional submissions dated 22.09.2022, wherein they reiterated their earlier written submissions with respect to the classification of the impugned products, including reference to the Supreme Court Judgment in the case **Span Diagnostics Ltd. Vs. CCE – 2007 (211) ELT 521 (SC)**

DISCUSSIONS AND FINDINGS

18. We have carefully gone through the entire appeal memorandum containing the submissions made by the Appellant vis-a-vis the Advance Ruling passed by the MAAR, wherein the MAAR has held that CRP kit and Hb1Ac kit do not fall under HSN code 3002 as the same would be covered by HSN Code 3822. The MAAR has based its ruling on the finding that Entry No.125 of List 1 of Sr. No. 180 of Schedule I of Notification No.1/2017-Central Tax (Rate), dated 28.6.2017, mentions the word "Agglutinating Sera", which is not followed by the word 'diagnostic kits', whereas, there are other entries in the same List 1 wherein there is a specific mention of diagnostic kit. The MAAR has further observed that "Agglutinating Sera" listed under Sr. No. 125 of List 1 of Schedule I covers agglutinating sera as an individual product, and not as a diagnostic kit which works on the principle of "Agglutinating Sera".

19. On perusal of the case records including facts of the case, the MAAR Order, and the grounds of appeal, the moot issues before us is as follows:

"whether the impugned products, i.e., CRP Test Kit and Hb1Ac Test Kit, comprising of various components, can be construed as agglutinating sera, or otherwise, in light of their product literatures dealing in with their constitution, working principles, and their functionalities".

20. Before delving into the aforesaid moot issue, we would like to examine the term 'antisera'. The meaning of it is provided in the HSN explanatory notes issued by the World Customs

Organization. It is the global body for assistance in the classification of the various products. The relevant extract as per the said explanatory notes is being reproduced hereunder:

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.

20.1 Thus it is clear that sometimes body cannot produce its own antibodies. So antigens of the pathogenic organism (bacteria, virus, etc.) is introduced into an animal body to produce antibodies. Then the antibodies created in the animal are extracted & introduced them into human body. These are known as antisera.

21. Now, we would like to examine the constitution, working principles, and functionalities of the impugned products, i.e., CRP Test Kit and Hb1Ac Test Kit, as per the product literature submitted by the Appellant.

21.1 According to the **product literature** pertaining to CRP Test Kit, which is also known as Turbilatex CRP, is a reagent set for quantitative determination of C-Reactive Protein in human serum based on Turbidimetric method. It is used to detect the inflammation and infection in the human body. It comprises of three components, which are (i) Buffer Reagent, (ii) Latex Reagent, and (iii) Calibrator Lyoph Serum Vial. CRP Test Kit is based on agglutination principle between latex particles coated with specific anti-human CRP and CRP present in the human serum to determine CRP in the sample, which is detected by a spectrophotometer device. It is submitted by the Appellant that the essential component of the CRP Test Kit is the latex particles coated with the anti –CRP antibody, which is nothing but antiserum, and is primarily responsible for the initiation of the reaction. It leads to agglutination and the ultimate diagnosis of the inflammation and infection, if any. It is further submitted that around 85% of the total cost of the CRP Test Kit is attributable to the latex particles coated with the anti-human CRP antibody, i.e., antisera. The Appellant has further submitted that the said anti human CRP antibody coated on the latex beads for the quantitative determination of CRP present in the human blood samples are nothing but the antisera drawn from mice.

21.2 On the basis of above reasoning, the Appellant has contended that since the essential component of the subject CRP Test kit is the antisera extracted from mice sera, which is being used for the

diagnostic purposes, the entire CRP Test Kit can aptly be construed as antisera in terms of its meaning provided under the HSN explanatory note, (cited supra), and accordingly, can be classified under the Chapter Heading 3002 in terms of the explanatory note (E) to the Chapter Heading 30.02, which is being reproduced hereunder:

"(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, hem agglutination, enzyme-linked immunosorbent assay (ELISA), etc. Malaria diagnostic kits monoclonal antibodies to pLDI-1 (plasmodium lactate dehydmgenase) 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."

21.3 Thus on perusal of the above explanatory note, it is clear that the diagnostic kits can also be classified under the Chapter Heading 30.02 where the essential component of the kit to be classified is the one falling under the Chapter head 30.02. It is further provided under the aforementioned explanatory note that the common reaction occurring in such kits would inter alia include agglutination. As regards the aforesaid provisions of the explanatory note to the Chapter Heading 30.02, it is observed here that the anit-human CRP antibody, i.e., antisera coated on the latex particles is the essential component of the impugned CRP Test Kit as discussed earlier and the reaction which occurs in the subject test kit is agglutination. Further, as has been discussed earlier, the essential character of the subject kit is given by the latex particles coated with anti-human CRP antibody, i.e., antisera, as it is the determining component for the agglutination which is the essentially the specificity of the test procedure. Therefore, the subject CRP Test Kit, being in the nature of a diagnostic kit for determining inflammation and infection in the human body, and satisfies all the conditions prescribed under the said explanatory note (E) to the Chapter heading 30.02, would aptly be covered under the Chapter Heading 30.02.

21.4 The explanatory note by World Customs Organization to Chapter 38.22 also clarifies that, *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 whether or not on a backing other than those of heading 3002 or 3006.

21.5 The impugned product CRP Test kit is based on mice anti- CRP antibody / mice antisera and thus covered under Chapter 30.02 as it is specifically excluded from Chapter 38.22. Chapter Heading 30.02 is the default entry for diagnostic kits. If any product is covered by Chapter 30.02, then there is no need to visit Chapter 38.22.

22.1 The Appellant have further submitted that the said impugned product, CRP Test Kit, will not be classified under the Chapter Heading 3822 attributable to its description which categorically excludes the diagnostic or laboratory reagent falling under the heading 3002. In support of its contention, the Appellant has cited the Supreme court judgment in the case of **Span Diagnostics Ltd. Vs. CCE, Surat – 2007 (211) ELT 521 (SC).**

22.2 On perusal of the aforementioned judgment, it is observed that the ratio of it is squarely applicable in the present case of classification of the subject product, i.e., CRP Test Kit. Here, we would like to refer to the relevant portion of judgement, wherein the Hon'ble Apex Court has observed as under:

> ***"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."***

22.3 After applying the ratio of the aforesaid judgment of the Hon'ble Supreme Court, it is observed that CRP Test Kit, the impugned product, whose principal component is the latex particles coated with the anti-human CRP antibody obtained from the mice antisera, will aptly be construed as antisera. Accordingly, it will be classified under the Chapter Heading 30.02, and not under the Chapter Heading 38.22 owing to its description wherein it is categorically mentioned that a diagnostic or laboratory reagents which are not falling under the Chapter Heading 30.02 will be covered under the Chapter Heading 38.22. The SC in the case of Span (cited supra) has held that

"merely because the medium used in latex (rubber) or paper will not bring the items under Chapter Heading 30.02". Since, the product under question is aptly classifiable under the Chapter Heading 30.02, therefore, the said impugned product, i.e., CRP Test Kit, will not be classified under the Chapter Heading 38.22.

23. Now, we proceed to decide the moot issue as to whether the impugned product, i.e., CRP Test Kit, can be construed as "agglutinating sera" mentioned at Sl. No. 125 of the List I appended to the Schedule I to the Notification No. 01/2017-C.T. (Rate) dated 28.06.2017, or not. In this regard, it is not in dispute that the said impugned product works on the principle of agglutination where the latex beads coated with the antisera reacts with the CRP of the human blood sample resulting into agglutination, which ultimately leads to diagnosis of inflammation or infection in the human body with the help of spectrophotometer. In view of this, it is held that the impugned product, i.e., CRP Test kit, which has been held as antisera, and which works on the principle of agglutination for the medical diagnosis of infection and inflammation in the human body, can aptly be construed as agglutinating sera.

24.1 The MAAR in the impugned order has observed that the Entry No.125 of List 1 appended to the Notification No.1/2017-Central Tax (Rate), dated 28.6.2017 mentions the word "Agglutinating Sera", and the said Entry does not mention the word 'diagnostic kits' whereas there are other entries in the same List 1 wherein there is a specific mention of diagnostic kit with respect to certain products. Therefore, "Agglutinating Sera" mentioned under Sr. No. 125 of List 1 of Schedule I covers agglutinating sera as an individual product, and not as a diagnostic kit, which works on the principle of "Agglutinating Sera". Thus, on the basis of aforesaid observation, the MAAR has held that the impugned products cannot be covered under "Agglutinating Sera" mentioned under Sl. No. 125 of the List I appended to the Schedule I to the Notification No. 01/2017-C.T. (Rate) dated 28.06.2017.

24.2 In this regard, we are in dissonance with the aforesaid observations made by the MAAR in as much as it is adequately clear from the plain reading of the HSN explanatory note that "antisera" covered under Chapter heading 3002 can be used for diagnostic purposes, including in vitro tests, which works on the principle of agglutination. It is further observed that List 1 appended to the Schedule-I to the Notification No. 01/2017-C.T. (Rate) dated 28.06.2017 enumerates only the medicines, drugs, and the diagnostic kits as mandated under the description of entry at Sl. No. 180 of the Notification No. 01/2017-C.T. (Rate). Since it is beyond doubt that the agglutinating sera cannot be construed as medicine or drug, therefore, the same is bound to be considered in the nature of diagnostic kit. Therefore, the observation of the MAAR that the agglutinating sera

mentioned under the said list 1 is an individual product and cannot be construed as diagnostic kit is not correct.

24.3 The MAAR had deduced that since the GST rate on certain products, including CRP (C-Reactive Protein), was reduced to 5% as per Sr. No. 7 of Notification No. 05/2021-Central Tax (Rate) dated 14.6.2021, and the notification was in operation up to 30.9.2021, the rate of CRP kit was 12%. Though such notification was indeed in operation for certain period, the MAAR has failed to appreciate that the notification covered both the Chapter Headings i.e.3002 and 3822.

25. In view of above discussion and findings in above paras, we hold that the impugned product will fall under entry "agglutinating sera" at Sl. No. 125 of the list I appended to the Schedule I to the Notification No 01/2017-C.T. (Rate) dated 28.06.2017. The said product, CRP Test Kit, will attract GST at the rate of 5% (CGST @ 2.5%+SGST@2.5%) in terms of the entry at Sl. No. 180 of Schedule I to the Notification No. 01/2017-C.T. (Rate) dated 28.06.2017

26. **We will now proceed to examine the classification and rate of tax in respect of another impugned product Hb1Ac Test Kit.**

26.1 As per the product literature and the submissions made by the Appellant in respect of the second impugned product, i.e., Hb1Ac Test Kit, it is seen that Hb1Ac Test Kit, much like the CRP Test Kit, is also a diagnostic kit having different components such as (i) Latex reagent, (ii) Buffered antibody reagent, (iii) Hemolysis Reagent, and (iv) Optional - Calibrator made from human blood, which works on the same principle of the agglutination as was the case with CRP Test kit. Further, as was the case with first impugned product, i.e., CRP Test kit, the principal component of the product under question is the antibody reagent, which is extracted from the antisera of the animals like mouse and goat, and which is primarily responsible for the agglutination process based on the interaction between the antibody and antigen, and which accounts for 75 % of the total cost of the impugned product. It is also seen that the impugned product under question is used for quantitative determination of hemoglobin A1c (HbA1c) in human blood and monitoring of glycemic control in diabetic patients. Thus, the impugned product is used as a diagnostic kit similar to that of CRP Test kit.

26.2 Thus, in view of the above facts, it is unequivocally clear that the second impugned product, i.e., HbA1c, is very similar to the first impugned product, i.e., CRP Test kit, in terms of its constitutionality and functionality, and hence all the reasoning and rationale used for classification of the first impugned product, i.e., CRP Test kit, will apply mutatis-mutandis to the second impugned product, i.e., HbA1c, too. Thus, it is held that second impugned product, i.e., HbA1c, will be classified under the chapter heading 3002, and accordingly, will attract GST at the rate of 5% (CGST @2.5 % +SGST @2.5 %).

27. Thus, in view of the above discussions and findings, we pass the following order:

ORDER

28. We, hereby, set aside the MAAR Order No. GST-ARA-98/2019-20/B-72 dated 11.10.2021 by holding that both the impugned products, i.e., CRP Test Kit and HbA1c Test kit, will be classified under chapter heading 3002, and accordingly, both the product will attract GST at the rate of 5% (CGST @2.5 % +SGST @2.5 %) in terms of the entry at Sl. No. 180 of the Schedule I to the Notification No. 01/2017-C.T. (Rate) dated 28.06.2017 read with entry at Sl. No. 125 of the List I appended to the Schedule I to the Notification No. 01/2017-C.T. (Rate) dated 28.06.2017. Thus, the appeal filed by the Appellant is, hereby, allowed.

(RAJEEV KUMAR MITAL)
MEMBER

(ASHOK KUMAR MEHTA)
MEMBER

Copy to the:

1. **Appellant;**
2. **AAR, Maharashtra**
3. **Pr. Chief Commissioner, CGST and Central Excise, Mumbai Zone.**
4. **Commissioner of State Tax, Maharashtra.**
5. **Deputy Commissioner MUM-VAT-E-624 LTU-2 Mumbai.**