

# ALL INDIA INSTITUTE OF MEDICAL SCIENCES BILASPUR (H.P)

Ref. No. Emergency & Trauma/2023-87.

Dated:24.04.2023

Subject: Consumables for ABG Machine on proprietary basis- Inviting
Comments thereon

A demand received from <u>Emergency and Trauma AIIMS Bilaspur (H.P.)</u> for the procurement of above cited items (Consumables for **ABG Machine**) on proprietary basis. The product is proprietary product of <u>SIEMENS</u> <u>HealthcareDiagnostics Inc USA</u>. The PAC certificate from the firm and its authorized suppler are attached and uploaded on website.

The above documents are being uploaded for open information to all, firms to submit the objections, with respect to proprietary nature of the product, if any within 15 days from the date of issue/uploading of the notification, giving reference no. **Emergency&Trauma/2023-87.** The objections/comments should be sent to storeofficer@aiimsbilaspur.edu.in or Procurement Officer, AIIMS Bilaspur (HP) 174037, on or before 08.05.2023 up to 5:00 PM, failing which it will be presumed that any other vendor is having no comments to offer and the case will be decided on merit.

Faculty In charge (Procurement)

Encl: Related Documents Enclosed

- 1) PAC certificate
- 2) Authorization certificate



### PROPRIETARY CERTIFICATE

INDIA / TRAID 833



15 January 2021

To Whom It May Concern

This is to certify that the following products listed in ANNEXURE-I are proprietary products of Siemens Healthcare Diagnostics Inc, located at 511 Benedict Avenue, Tarrytown, NY 10591 USA.

We, Siemens Healthcare Pvt Ltd., having registered address at Siemens Healthcare Pvt Ltd, DLF Cyber City, Phase II, Upper Ground Floor, DLF Building No. 10, Tower A, Gurgaon 122002, Haryana, India is the sole authorized representative for the sales & distribution of this product in India directly or through its authorized distributor.

#### ANNEXURE-I

SMN	Product Description
11416755	RAPIDPoint 500e Blood Gas Analyzer ROW
10844813	RAPIDPoint 500 Measurement Cartridge LAC 100 Test
10491447	RAPIDPoint 500 Measurement Cartridge LAC 250 Test
10491448	RAPIDPoint 500 Measurement Cartridge LAC 400 Test
10491449	RAPIDPoint 500 Measurement Cartridge LAC 750 Test
10329097	Wash/Waste Cartridge (4)
10310323	Automatic QC Cartridge Kit

Lois Parillon

Regulatory Technical Specialist

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1-15-2031

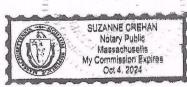
COMMONWEALTH OF MASSACHUSETTS COUNTY OF BRISTOL

On this <u>15<sup>th</sup></u> day of <u>January</u>, <u>2021</u> before me, the undersigned Notary Public, <u>Lois Parillon</u>, personally appeared, proved to me through satisfactory evidence of identification, which is <u>personally known to me</u>, to be the person whose name is signed on this letter in my presence.

I hereunto set my hand and official seal,

SIEMENS Healthcare Diagnostics Inc.

511 Benedict Avenue 2 Edgewater Drive



ARRRYTOWN, NY 10591 USA NORWOOD, MA 02062 USA



## ALL INDIA INSTITUTE OF MEDICAL SCIENCES BILASPUR (H.P)

Ref. No. Emergency& Trauma/2023-90.

Dated:24.04.2023

Subject: Consumables for Point Of Care Machine on proprietary basis- Inviting

Comments thereon

A demand received from <u>Emergency and Trauma AIIMS Bilaspur (H.P.)</u> for the procurement of above cited items (Consumables for <u>Point Of Care Machine</u>) on proprietary basis. The product is proprietary product of <u>Quidel Cardiovascular Inc.</u> The PAC certificate from the firm and its authorized suppler are attached and uploaded on website.

The above documents are being uploaded for open information to all, firms to submit the objections, with respect to proprietary nature of the product, if any within 15 days from the date of issue/uploading of the notification, giving reference no. **Emergency&Trauma/2023-90.** The objections/comments should be sent to storeofficer@aiimsbilaspur.edu.in or Procurement Officer, AIIMS Bilaspur (HP) 174037, on or before 06.05.2023 up to 5:00 PM, failing which it will be presumed that any other vendor is having no comments to offer and the case will be decided on merit.

Faculty In charge (Procurement)

Encl: Related Documents Enclosed

- 1) PAC certificate
- 2) Authorization certificate





February 19, 2021

To Whom It May Concern

Sub.: PROPRIETARY CERTIFICATE

This is to certify that the below mentioned products along-with the catalogue no.'s are the proprietary items, manufactured by us. M/S Quidel Cardiovascular Inc, 9975 Summers Ridge Road, San Diego, CA 92121, USA.

SL No.	Product Name	Specific Intended Use	Catalogue No.
1	Quidel Triage <sup>*</sup> MeterPro	The Quidel Triage MeterPro is a portable fluorescence instrument used to measure the results of tests manufactured by Quidel Cardiovascular Inc. The Quidel Triage MeterPro can be used in a laboratory or in a point-of-care setting.	55071
2	Quidel Triage <sup>®</sup> Total 3 Control 1	The Quidel Triage Total 3 Controls are assayed materials to be used with the Quidel Triage Troponin I Test, Quidel Triage BNP Test, Quidel Triage Cardio2 Panel and Quidel Triage Cardio3 Panel devices and the Quidel Triage Meter to assist the end user in monitoring product performance.	88733
3	Quidel Triage* Total 3 Control 2	The Quidel Triage Total 3 Controls are assayed materials to be used with the Quidel Triage Troponin I Test, Quidel Triage BNP Test, Quidel Triage Cardio2 Panel and Quidel Triage Cardio3 Panel devices and the Quidel Triage Meter to assist the end user in monitoring product performance.	88734
4	Quidel Triage <sup>®</sup> Total 5 Control 1	The Quidel Triage Total 5 Controls are assayed materials to be used with the Quidel Triage Cardiac Panel, Quidel Triage Profiler SOB Panel, Quidel Triage BNP Test, Quidel Triage D-Dimer Test, and Quidel Triage Meters to assist the laboratory in monitoring test performance.	88753
5	Quidel Triage <sup>®</sup> Total 5 Control 2	The Quidel Triage Total 5 Controls are assayed materials to be used with the Quidel Triage Cardiac Panel, Quidel Triage Profiler SOB Panel, Quidel Triage BNP Test, Quidel Triage D-Dimer Test, and Quidel Triage Meters to assist the laboratory in monitoring test performance.	88754
6	Quidel Triage <sup>*</sup> Total 5 Calibration Verification	The Quidel Triage Total 5 Calibration Verification materials are to be used with the Quidel Triage Cardiac Panel, Quidel Triage Profiler SOB Panel, Quidel Triage BNP Test, Quidel Triage D-Dimer Test and Quidel Triage Meters to verify the calibration of the Test Devices throughout the measurable range.	88755
7	Quidel Triage <sup>®</sup> TOX Drug Screen	The Quidel Triage TOX Drug Screen is a fluorescence immunoassay to be used with the Quidel Triage Meters for the qualitative determination of the presence of drug and/or the major metabolites above the threshold concentrations of up to 10 distinct drug classes, including assays for	94400EU

SL No.	Product Name	Specific Intended Use	Catalogue No
		acetaminophen/paracetamol, amphetamines, methamphetamines, barbiturates, benzodiazepines, cocaine,	
		methadone, opiates, phencyclidine, THC and tricyclic antidepressants in urine. The acetaminophen/paracetamol assay	
		will yield positive results when acetaminophen/paracetamol is	
		ingested at or above therapeutic doses. This test provides only a	
		preliminary result. Clinical consideration and professional	***************************************
		judgment must be applied to any drug of abuse test result,	
		particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate	
1		chemical method is needed. Gas Chromatography/Mass	
		Spectrometry (GC/MS), Liquid Chromatography/ Mass	
		Spectrometry/ Mass Spectrometry (LC/MS/MS) and High	
		Performance Liquid Chromatography (HPLC) are common	
		confirmatory methods. A quantitative serum	
		acetaminophen/paracetamol measurement is the common	
		confirmatory method for preliminary positive	
		acetaminophen/paracetamol results.	
8	Quidel Triage* TOX	The Quidel Triage TOX Drug Screen Controls are to be used with	94413
	Drug Screen Control	the Quidel Triage TOX Drug Screen tests and Quidel Triage	
	1	Meters to assist the end user in monitoring product performance.	
9	Quidel Triage* TOX	The Quidel Triage TOX Drug Screen Controls are to be used with	94414
	Drug Screen Control	the Quidel Triage TOX Drug Screen tests and Quidel Triage	
10	Quidel Triage*	Meters to assist the end user in monitoring product performance.	97000HSEU
10	Cardiac Panel	The Quidel Triage Cardiac Panel is a fluorescence immunoassay to be used with the Quidel Triage Meters for the quantitative	970000350
	cardiac ranci	determination of creatine kinase MB (CK-MB), myoglobin and	
		troponin I in EDTA anticoagulated whole blood or plasma	
		specimens. The test is used as an aid in the diagnosis of	
		myocardial infarction (injury).	
11	Quidel Triage*	The Quidel Triage Profiler SOB™ (Shortness of Breath) Panel is a	97300EU
1	Profiler SOB™ Panel	fluorescence immunoassay to be used with the Quidel Triage	
Ý		Meters for the quantitative determination of creatine kinase MB,	
		myoglobin, troponin I, B-type natriuretic peptide, and cross-	
		linked fibrin degradation products containing D-dimer in EDTA	
		anticoagulated whole blood and plasma specimens. The test is	
		used as an aid in the diagnosis of myocardial infarction (injury), an aid in the diagnosis and assessment of severity of heart	
		failure, an aid in the risk stratification of patients with heart	
		failure, an aid in the assessment and evaluation of patients	
		suspected of having disseminated intravascular coagulation or	
		thromboembolic events including pulmonary embolism and an	
		aid in the risk stratification of patients with acute coronary	
		syndromes.	
12	Quidel Triage"	The Quidel Triage Cardio3 Panel is a fluorescence immunoassay	
	Cardio3 Panel	to be used with the Quidel Triage Meters for the quantitative	97400EU
	-	determination of creatine kinase MB, troponin I, and B-type	
		natriuretic peptide in EDTA anticoagulated whole blood and	
		plasma specimens. The Quidel Triage Cardio3 Panel is to be used	
		as an aid in the diagnosis of myocardial infarction (injury), an aid	

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SL No.	Product Name	Specific Intended Use	Catalogue No
	,	in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure), an aid in the risk stratification of patients with heart failure, and an aid in the risk stratification of patients with acute coronary syndromes.	
13	Quidel Triage <sup>®</sup> Cardio2 Panel	The Quidel Triage Cardio2 Panel is a fluorescence immunoassay to be used with the Quidel Triage Meters for the rapid quantitative determination of troponin I and B-type natriuretic peptide in EDTA anticoagulated whole blood and plasma specimens. The Quidel Triage Cardio2 Panel is to be used as an aid in the diagnosis of myocardial infarction (injury), an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure), an aid in the risk stratification of patients with heart failure, and an aid in the risk stratification of patients with acute coronary syndromes.	97500EU
14	Quidel Triage <sup>*</sup> BNP Test	The Quidel Triage BNP Test is a rapid, point of care fluorescence immunoassay to be used with the Quidel Triage Meters for the quantitative measurement of B-type natriuretic peptide (BNP) in EDTA anticoagulated whole blood or plasma specimens. The test is intended to be used as an aid in the diagnosis and assessment of severity of congestive heart failure (also referred to as heart failure). The test also is used for the risk stratification of patients with acute coronary syndromes and for the risk stratification of patients with heart failure.	98000XREU
15	Quidel Triage <sup>®</sup> BNP Control 1	The Quidel Triage BNP Controls are assayed materials to be used with the Quidel Triage BNP Test and Quidel Triage Meter to assist the end user in monitoring product performance.	98013XR
1.6	Quidel Triage <sup>*</sup> BNP Control 2	The Quidel Triage BNP Controls are assayed materials to be used with the Quidel Triage BNP Test and Quidel Triage Meter to assist the end user in monitoring product performance.	98014XR
17	Quidel Triage® BNP Calibration Verification	The Quidel Triage BNP Calibration Verification materials are to be used with the Quidel Triage BNP Test and Quidel Triage Meter to verify the calibration of the Quidel Triage BNP Test throughout the measurable range.	98015XR
18	Quidel Triage <sup>®</sup> D- Dimer Test	The Quidel Triage D-Dimer Test is a fluorescence immunoassay to be used with the Quidel Triage Meters for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA anticoagulated whole blood and plasma specimens. The test is used as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism.	98100EU
19	Quidel Triage <sup>*</sup> Troponin I Test	The Quidel Triage Troponin I Test is a fluorescence immunoassay to be used with the Quidel Triage Meters for the quantitative determination troponin I in EDTA anticoagulated whole blood and plasma specimens. The test is used as an aid in the diagnosis of myocardial infarction (injury).	98600EU
20	Quidel Triage* NT- proBNP Test	The Quidel Triage NT-proBNP Test is a fluorescence immunoassay to be used with the Quidel Triage Meter for the quantitative determination of N-terminal pro-Brain Natriuretic Peptide (NT-	
	and the second s	proBNP) in EDTA anticoagulated whole blood and plasma	98700EU

SL No.	Product Name	Specific Intended Use	Catalogue No.
		specimens. The test is to be used as an aid in the diagnosis of individuals suspected of having congestive heart failure (also referred to as heart failure). The test is also to be used as an aid for the risk stratification of patients with heart failure and the risk stratification of patients with acute coronary syndromes (ACS). The test may also serve as an aid in the assessment of increased risk for cardiovascular events and mortality in patients at risk for	
21	Quidel Triage* NT- proBNP Control 1	heart failure who have stable coronary artery disease.  The Quidel Triage NT-proBNP Controls are assayed materials to be used with the Quidel Triage NT-proBNP Test and the Quidel Triage Meter to assist the end user in monitoring product performance.	98713EU
22	Quidel Triage* NT- proBNP Control 2	The Quidel Triage NT-proBNP Controls are assayed materials to be used with the Quidel Triage NT-proBNP Test and the Quidel Triage Meter to assist the end user in monitoring product performance.	98714EU
23	Quidel Triage® BNP Reagents	The Quidel Triage BNP test is intended for use with the Beckman Coulter Access Family of Immunoassay Systems for the In Vitro quantitative measurement of B-type natriuretic peptide (BNP) in plasma specimens using EDTA as the anticoagulant. The test is intended to be used for the following indications:  - as an aid in the diagnosis of congestive heart failure (also referred to as heart failure)  - as an aid in the assessment of severity of congestive heart failure  - for the risk stratification of patients with acute coronary syndromes  - for the risk stratification of patients with heart failure	98200
24	Quidel Triage® BNP QC Controls	The Quidel Triage BNP QC Controls are intended for monitoring the performance of the Quidel Triage BNP test using the Beckman Coulter Access Family of Immunoassay Systems.	98201
25	Quidel Triage® BNP Calibrators	The Quidel Triage BNP Calibrators are intended to calibrate the Quidel Triage BNP test for the quantitative determination of BNP levels in human EDTA plasma using the Beckman Coulter Access Family of Immunoassay Systems.	98202

Ruchael Strike

Signature of the Manufacturer or on Behalf of the Manufacturer (Rachael S. Williamson, Associate Director, Regulatory Affairs)





Dated: 25.03.2023

#### MANUFACTURER'S AUTHORISATION FORM

The Director, AHMS, Bilaspur

Dear Sir.

Ref: Quotation for purchase of consumables for Point of Care Device (Cardiac Biomarker)

We. Quidel Corp., who are proven and reputable manufacturers of Point of Care Device (Cardiac Biomarker) having factories at 9975 Summers Ridge Drive, San Diego, CA 92121 USA hereby authorize Messrs Jolly Technocrats. 304, Mansarovar Building-90, Nehru Place, New Delhi -110019 to supply consumables for Point of care device (Cardiac Biomarker) to your institute.

No other company is authorized to quote or supply to your institute.

We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly"

Yours faithfully,

