



DEPARTMENT OF THE NAVY
 NAVSUP FLEET LOGISTICS CENTER SIGONELLA
 DET NAPLES, ITALY
 PSC 817 BOX 50
 FPO AE 09622-0050

J&A Number: 16-029

JUSTIFICATION AND APPROVAL
 FOR USE OF SOLE SOURCE

1. Contracting Activity.

The requiring activity is U.S. Naval Hospital Naples in Naples, Italy. The contracting activity is NAVSUP Fleet Logistics Center Sigonella (FLCSI) Site Naples.

2. Description of the Action Being Approved.

This justification and approval (J&A) authorizes the establishment of an indefinite-delivery indefinite-quantity (IDIQ) contract with firm fixed price (FFP) line items with Cidichem S.r.l. The contract will be for the lease of two Ortho Clinical Diagnostics (formerly Johnson & Johnson) Vitros 5600 chemistry analyzers, lease of two Vitros 350 chemistry analyzers, and procurement of associated Vitros reagents and supplies on a cost-per-test, sole source basis. These instruments are used to provide critical care immunochemistry on patients, as requested by health care providers. This critical care testing includes cardiac markers, liver enzymes, kidney function, and other testing needed for emergent patient care, which is essential to successful hospital operation.

3. Description of Supplies/Services.

The requirement consists of:

- a. Lease, installation, maintenance and technical support of two Vitros 5600 clinical chemistry testing systems; on-site training on the new features of the system; and operations update.
- b. Procurement of specialized reagents and supplies for the Vitros 5600 systems. Refer to Exhibit B of this J&A for detailed list.
- c. Lease, maintenance and technical support for two Vitros 350 clinical chemistry testing systems already in place at U.S. Naval Hospital Naples.
- d. Procurement of specialized reagents and supplies for the Vitros 350 systems. Refer to Exhibit A of this J&A for detailed list.

Period of performance for lease of the Vitros 5600 systems will be for a total of 36 months, consisting of ordering periods not exceeding one year. The first ordering period will be from 1 January 2017 to 31 December 2017 followed by two ordering periods of one year each.

The estimated total cost for the Vitros 5600 systems, the reagents and tests on a cost-per-test basis is as follows:

Period	Dates	Est. € Value	Est. \$ Value*
Year 1	1 January 2017 – 31 December 2017		
Option 1	1 January 2018 – 31 December 2018		
Option 2	1 January 2019 – 31 December 2019		
	Total		

* Budget Exchange Rate used is Fiscal Year 2017 (\$1 = Euro 0.8990) foreign currency fluctuation budget rate obtained from the Office of Secretary of Defense (Comptroller).

Period of performance for the lease of the Vitros 350 systems will be for a total of 6 months beginning from 1 January 2017 until 30 June 2017. It is noted that the period of performance required to support the Vitros 350 model is only 6 months because the Navy hospital system is transitioning away from this model and moving exclusively to the 5600 model discussed above.

The estimated total cost for the Vitros 350 systems, the reagents and tests on a cost-per-test basis is as follows:

Period	Dates	Est. € Value	Est. \$ Value*
Year 1	1 January 2017 – 30 June 2017		

* Budget Exchange Rate used is Fiscal Year 2017 (\$1 = Euro 0.8990) foreign currency fluctuation budget rate obtained from the Office of Secretary of Defense (Comptroller).

Thus, the total estimated value of this requirement is as follows:

	Est. € Value	Est. \$ Value*
Vitros 5600		
Vitros 350		
Total		

4. Statutory Authority Permitting Other Than Full and Open Competition.

The statutory authority for this acquisition permitting other than full and open competition is 41 U.S.C. 1901, "(Only one responsible source)," as implemented by FAR 13.501(a)(1)(ii).

5. Rationale Justifying Use of Cited Statutory Authority.

USNH Naples currently utilizes the Ortho Clinical Diagnostics Vitros 350 analyzers for their Clinical Chemistry testing needs. The Vitros analyzers utilize a "dry-slide" technology which operates without a water source.

There are two types of chemistry analyzer systems currently available in the commercial marketplace: water based systems and non-water based (dry-slide technology) systems. USNH Naples requires a non-water based system because the hospital does not have the infrastructure to support a water based system. In order to support a water based system, the hospital would require extensive remodeling of its existing infrastructure; specifically, USNH would need to purchase a high grade water purification system, water softener, as well as either the installation of a self-contained on-board liquid waste management system or extensive modifications to the plumbing/drainage system to accommodate such a system. Furthermore, water-based analyzers would also incur additional annual maintenance costs to maintain pumps and tubing to prevent a potential breakdown that would result in work stoppages. Additionally, USNH's biohazard waste disposal costs would increase with the additional liquid waste generated. The water-based system would also require 23,594 additional reagents, controls, and calibrators compared to 3,448 required to operate the dry-slide system. Thus, the necessary investment costs of extensive remodeling of existing infrastructure in order to completely change its chemical analyzer system far outweigh the benefits of doing so.

USNH Naples POC, LT Nance, and the Negotiator researched if this machine was used in other locations. Research was performed through phone calls and through EDA and FPDS searches and it

was found that several locations used this equipment. This was also confirmed by the personnel that come in from other duty stations. Further, it takes 30-40 hours to train an operator to become proficient on a water based system (source <http://www.orthoclinical.com/en-us/services/training-education>), thereby adding to the investment costs associated with transitioning to such a system. As such, transition to any water based system is cost prohibitive.

The aforementioned Vitros models meet FDA and CAP requirements and were subjected to a rigorous approval process, and are approved by the Navy Specialty Leader. US Navy locations that currently use the Vitros analyzers include, but are not limited to: Naval Health Clinic New England in Groton, CT; Naval Air Station Sigonella, Italy; Kandahar Regional Military Hospital; Naval Medical Center Portsmouth, NH; and in USNS Mercy (T-AH-19). There are no other types of non-water based systems currently in use in US Navy medical centers and hospitals. The Navy has invested significantly in Vitros equipment and associated training, and all hospital personnel are trained on this brand name equipment. The use of a different non-water based analyzer would impose undue burden on the requiring activity due to training for rotating personnel and performance of its chemistry analysis program. Navy personnel rotating into the Naples hospital will have already been trained on the Vitros systems and use of a different system will risk impact to the quality and timeliness of patient care. Thus, investing in a different line of equipment would result in substantial duplication of cost to the Government that is not expected to be recovered through competition.

Currently, two Vitros 350 systems are in place and have been used in the Naples hospital under contract N68171-12-D-0003 since 2012, and the hospital will soon begin transitioning to the Vitros 5600 model. In order to transfer testing to the new Vitros 5600 systems, the old and new systems are required to be used side by side for a period of 6 months so comparative testing can be completed. The Vitros 5600 systems will not be available until 1 January 2017, so the lease on the current Vitros 350 systems needs to also be included in the new contract.

Ortho Clinical Diagnostics confirmed that Cidichem Srl is the only distributor authorized to deliver reagents and supplies to USNH Naples as shown in their exclusivity letter dated 17 June 2016.

6. Description of Efforts Made to Solicit Offers from as Many Offerors as Practicable.

Members of technical and contracting teams conducted market research to determine the availability of additional clinical chemistry testing throughout the European region. Based on information gathered, the Vitros 5600 and 350 systems from Ortho Clinical Diagnostics are the only chemistry analyzers that offer the dry slide technology which can test clinical chemistry assays without a water source, and this model is the standard for Navy hospitals.

A sources sought for this planned contract was published on NECO on 11 August 2016 and no responses were received.

7. Determination of Fair and Reasonable Cost.

The Contracting Officer anticipates that the cost to the Government of the supplies and services covered by this J&A will be fair and reasonable. Price analysis will be conducted prior to award and documented to ensure fair and reasonable pricing.

8. Actions to Remove Barriers to Future Competition.

For the reasons set forth in Paragraph 5, no other viable sources of this equipment exist in Italy; however, if another potential source emerges, the contracting activity will assess whether competition for future requirements is feasible.

9. CONTRACTING POINT OF CONTACT

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Contract Specialist
FLCSI Site Naples
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EXHIBIT A
REAGENTS AND SUPPLIES - VITROS 350

ELIN	TEST ID	TEST NAME	PACK SIZE (TESTS)	PACK PER YEAR
A001AA	Art.: 8379034	SODIO Na+ 250 det. - SODIUM	250	12
A001AB	Art.: 8157596	POTASSIO K+ 250 det. ex cod. 1616200- POTASSIUM	250	12
A001AC	Art.: 8445207	CLORO 250 test - CHLORIDE	250	10
A001AD	Art.: 8262396	BICARBONATI "CO2" 5x60ts - ECO2	300	10
A001AE	Art.: 1707801	GLUCOSIO 5x60ts - GLUCOSE	300	16
A001AF	Art.: 8102204	BUN/UREA 300 test ex 1743418 - BUN	300	10
A001AG	Art.: 6802584	CREATININA 5x60 ex art. 8141947 - CREATININE	300	10
A001AH	Art.: 8196057	ALBUMINA 5x50ts - ALBUMIN	250	10
A001AI	Art.: 8159931	BILIRUBINA TOTALE 5x60ts - TOTAL BILIRUBIN	300	8
A001AJ	Art.: 8383051	BILIRUBINA BuBc 5x60ts - BUBC	300	6
A001AK	Art.: 1450261	CALCIO 5x60ts - CALCIUM	300	10
A001AL	Art.: 1669829	COLESTEROLO TOTALE 5x60ts - CHOLESTEROL	300	10
A001AM	Art.: 1513209	FOSFORO 5x60ts - PHOSPHORUS	300	10
A001AN	Art.: 8392292	PROTEINE TOTALI 5x50ts - TOTAL PROTEIN	250	10
A001AO	Art.: 1943927	ACIDO URICO 5x60ts - URIC ACID	300	6
A001AP	Art.: 1655281	GPT/ALT 5x50ts - ALT	250	10

A001AQ	Art.: 8433815	GOT/AST 5x60ts Transaminasi - AST	300	10
A001AR	Art.: 1053180	FOSFATASI ALCALINA 5x60ts ALKP - ALK PHOS	300	10
A001AS	Art.: 8384489	LDH 5x50ts - LDH	250	8
A001AT	Art.: 1336544	TRIGLICERIDI 5x60ts - TRIGLYCERIDES	300	10
A001AU	Art.: 8479396	CK Nac 300 det. - CK	300	16
A001AV	Art.: 8257289	GAMMA GT 5x50ts - GGT	250	8
A001AW	Art.: 1202670	AMILASI 5x60ts - AMYLASE	300	12
A001AX	Art.: 8297749	LIPASI 5x18ts - LIPASE	90	12
A001AT	Art.: 8255093	MAGNESIO 5x60ts - MAGNESIUM	300	10
A001AZ	Art.: 8001133	CK-MB 5x18ts - CKMB	90	12
A001BA	Art.: 8208431	Proteine totali in"CSF" 5x18ts - CSF PROTEIN	90	6
A001BB	Art.: 1314343	SALICILATI 5x18ts - SALICYLATE	90	6
A001BC	Art.: 8046872	ALCOOL 5x18ts - ALCOHOL	90	6
A001BD	Art.: 1037274	ACETOMINOFENE 90 test - ACET	90	6
A001BE	Art.: 6801895	COLESTEROLO HDL DIR.300 test - Direct HDL	300	10
A001BF	Art.8150112	LATTATO (90 ts) LACTATE	90	6
A001BG		ELECTROLITE REFERENCE FLUID	N/A	8
A001BH	Art.: 1882208	CAL-KIT 1 (4set) -18øc - Chem Cal Kit 1	N/A	4
A001BI	Art.: 1662659	CAL-KIT 2 (4set) -18ø - Chem Cal Kit 2	N/A	4
A001BJ	Art.: 1290709	CAL-KIT 3 (4set) -18øc - Chem Cal Kit 3	N/A	4

A001BK	Art.: 1204668	CAL-KIT 4 (4set) -18oc - Chem Cal Kit 4	N/A	4
A001BL	Art.: 1149764	CAL-KIT 5 (4set) 2-8oC - Chem Cal Kit 5	N/A	2
A001BM	Art.: 1204247	CAL-KIT 6 (4set) -18oC - Chem Cal Kit 6	N/A	2
A001BN	Art.: 8578163	CAL KIT 8 (Alcool) 2set +2 c - Chem Cal Kit 8	N/A	2
A001BO	Art.: 8568040	CAL KIT 9 (FARMACI) 2set - 18oc - Chem Cal Kit 9	N/A	4
A001BP	Art.: 6801896	CAL-KIT 25 (Col.hdl dir.) - Chem Cal Kit 25	N/A	2
A001BQ	Art.: 8262487	BSA 7% 12x5ml Albumina Bovina - 7% BSA	N/A	8
A001BR	Art.: 8067324	PERF.VERIF. I (12set) + I.S.Lotto - Performance Ver. 1	N/A	4
A001BS	Art.: 8231474	PERF.VERIFIER II (12set) + Ins.Sheet Lotto - Performance Ver. 2	N/A	4
A001BT	Art.: 8466492	LIQUID P.V. I (6set) +2°C + INSERT SHEET Lotto - Liquid per Ver. 1	N/A	4
A001BU	Art.: 1384007	LIQUID P.V. II (6set) +2°C + INSERT SHEET Lotto - Liquid per Ver. 2	N/A	4
A001BV	Art.: 8721508	ISO.P.V. I (6set) + INSERT SHEET Lotto - Isoenzymes PV1	N/A	8
A001BW	Art.: 8748220	ISO.P.V.II (6set) + INSERT SHEET Lotto - Isoenzymes PV2	N/A	8

A001BX	Art.: 8962540	TDM P.V. I (6x3ml) + INSERT SHEET LOT. - TDM 1	N/A	2
A001BY	Art.: 1792357	TDM P.V. II (6x3ml) + INSERT SHEET LOT. - TDM 2	N/A	2
A001BZ	6801876	CD Calibration disk	N/A	6
A001CA	6801892	Humidification Pack	N/A	16
A001CB	1250232	Dessiccant Pack	N/A	12
A001CC	6801715	Versa Tip	N/A	8
A001CD	6801423	FS Micro Tip	N/A	4
A001CE		Micro sample cups	N/A	4
A001CF		Sample Cup pierce cup	N/A	2
A001CG		FS Cuvette	N/A	6
A001CH	6802888	Versatip box container Unloading	N/A	6
A001CI	6802889	Couvette-microtip box.container Unloading	N/A	6
A001CJ	N/A	VITROS 350	12 MONTHS	2

EXHIBIT B
REAGENTS AND SUPPLIES – VITROS 5600

ELIN	TEST ID	TEST NAME	PACK SIZE	PACK PER YEAR
B002AA	1707801	Glucose	5 X 60 TEST	22
B002AB	8102204	Urea	5 X 60 TEST	18
B002AC	6802584	Creatinine	5 X 60 TEST	18
B002AD	1943927	Uric Acid	5 X 60 TEST	12
B002AE	8159931	Total Bilirubin	5 X 60 TEST	16
B002AF	8383051	Unconj./Coniugated Bilirubin	5 X 60 TEST	9
B002AG	1669829	Cholesterol	5 X 60 TEST	17
B002AH	6801895	Direct HDL Cholesterol	5 X 60 TEST	17
B002AI	1336544	Triglycerides	5 X 60 TEST	17
B002AJ	8392292	Total Protein	5 X 50 TEST	18
B002AK	8196057	Albumin	5 X 50 TEST	18
B002AL	8208431	CSF Protein	5 X 18 TEST	10
B002AM	8379034	Sodium	5 X 50 TEST	24
B002AN	8157596	Potassium	5 X 50 TEST	24
B002AO	8445207	Chloride	5 X 50 TEST	18
B002AP	1450261	Calcium	5 X 60 TEST	18
B002AQ	1513209	Phosphorus	5 X 60 TEST	18
B002AR	8255093	Magnesium	5 X 60 TEST	18
B002AS	8262396	Carbon Dioxide	5 X 60 TEST	18
B002AT	8433815	GOT/AST	5 X 60 TEST	18
B002AU	1655281	GPT/ALT	5 X 50 TEST	18
B002AV	8257289	GGT	5 X 50 TEST	14
B002AW	1053180	Alkaline Phosphatase	5 X 60 TEST	18
B002AX	8384489	LDH	5 X 50 TEST	16
B002AT	8478034	CK	5 X 18 TEST	30
B002AZ	8001133	CK-MB	5 X 18 TEST	24
B002BA	8112724	Amylase	5 X 18 TEST	23
B002BB	8297749	Lipase	5 X 18 TEST	24
B002BC	8150112	Lactate	5 X 18 TEST	12
B002BD	8046872	Alcohol	5 X 18 TEST	12
B002BE	1314343	Salicylate	5 X 18 TEST	8
B002BF	1037274	Acetaminophen	5 X 18 TEST	9
B002BG	6801728	Direct LDL	6 X 100 TEST	9
B002BH	1830033	Immuno Wash Fluid	30	10
B002BI	8057812	Electrolyte Reference Fluid	30	14
B002BJ	6801752	Diluent pack 1	3 X 55 ML	8

B002BK	6801753	Diluent pack 2	3 X 55 ML	8
B002BL	6801754	Diluent pack 3	3 X 55 ML	8
B002BM	6801873	FS Calibrator 1	12 X 3 ML	3
B002BN	6801874	Reconstituent Diluent	12 X 5 ML	3
B002BO	1882208	CAL KIT 1	4 SET.	11
B002BP	1662659	CAL KIT 2	4 SET.	11
B002BQ	1290709	CAL KIT 3	4 SET.	8
B002BR	1204668	CAL KIT 4	4 SET.	8
B002BS	1149764	CAL KIT 5	4 SET.	4
B002BT	1204247	CAL KIT 6	4 SET.	4
B002BU	1320498	CAL KIT 7	2 SET.	4
B002BV	8578163	CAL KIT 8	2 SET.	4
B002BW	8568040	CAL KIT 9	2 SET.	8
B002BX	6800189	CAL KIT 10	2 SET.	4
B002BY	6801703	CAL KIT 19	8 FIALE	4
B002BZ	6801896	CAL KIT 25	2 SET.	4
B002CA	6842906	CAL KIT 31	1 FIALA	4
B002CB	8067324	Performance Verifier I	12 X 3 ML	18
B002CC	8231474	Performance Verifier II	12 X 3 ML	18
B002CD	8466492	Liquid Performance Verifier I	6 X 2 ML	12
B002CE	1384007	Liquid Performance Verifier II	6 X 2 ML	12
B002CF	8721508	Isoenzyme Performance Verifier I	6 X 3 ML	14
B002CG	8748220	Isoenzyme Performance Verifier II	6 X 3 ML	14
B002CH	8962540	TDM Performance Verifier I	6 X 3 ML	8
B002CI	1792357	TDM Performance Verifier II	6 X 3 ML	8
B002CJ	6801755	HIT Performance Verifier I&II	2 X 3 ML	6
B002CK	6801876	CD Calibration disk	1	12
B002CL	6801892	Humidification Pack	1	30
B002CM	1250232	Essiccant Pack	2	20
B002CN	6801715	Versa Tip	1000	14
B002CO	6801423	FS Micro Tip	4096	8
B002CP	6801422	FS Cuvette	6000	3
B002CQ	1451392	Pierceable cap	1000	1

B002CR	6801967	FS cardrack filter	1	2
B002CS	6801965	FS Slide disposal liner	10	1
B002CT	1213115	Micro sample cups	4000	2
B002CU	6802888	Versatip box container Unloading	10	3
B002CV	6802889	Couvette-microtip box container Unloading	10	3
B002CW	1912997	TSH *	100 TEST	45
B002CX	6802220	Total β -hCG Generation II	100 TEST	20
B002CY	6842844	Total PSA II *	100 TEST	30
B002CZ	6802301	Troponin I ES*	100 TEST	40
B002DA	6802156	NT - pro BNP *	100 TEST	9
B002DB	1487289	Calibrators TSH	1 X 3 LIVELLI	14
B002DC	6802221	Calibrators β HCG II Gen.	3 X 3 LIVELLI	14
B002DD	6842849	Calibrator Total PSA II	1x2 Livelli	14
B002DE	6802302	Calibrators Troponin I ES	2 X 3 LIVELLI	14
B002DF	6802157	Calibrators NT-pro BNP	3 X 1 LIVELLI	14
B002DG	1072693	Signal reagent	400 TEST	24
B002DH	8389793	Wash reagent	2 X 5 LITRI	24
B002DI	8430373	Diluent A	100 TEST	24
B002DJ	8321200	Diluent B	100 TEST	24
B002DK	6800100	Adsorption filter	1 PZ.	6
B002DL	1831312	Maintenance Pack	2 PZ.	4
B002DM	N/A	VITROS 5600	12 MONTHS	2