

DEPARTMENT OF VETERANS AFFAIRS

Justification for Single Source Awards IAW [FAR 13.106-1](#)  
For  
Over Micro-Purchase Threshold but Not Exceeding the SAT (\$250K)

Acquisition Plan Action ID: 531-19-2-9961-0035

1. **Contracting Activity:** Department of Veterans Affairs, VISN 20, Boise VA Medical Center

Department of Veterans Affairs  
Network Contracting Office 20 (NCO 20)  
5115 NE 82<sup>nd</sup> Ave.  
Vancouver, WA 98662

2. **Brief Description of Supplies/Services required and the intended use/Estimated Amount:**

Leica Bond Max Processing Module  
Powervar Line Conditioner + Battery Backup  
Bond System Control

Item(s) required for laboratory use for processing biological material in diagnosis procedures.

3. **Unique characteristics that limit availability to only one source, with the reason no other supplies or services can be used:**

The program office has conducted extensive market research on this type of equipment and although they have found multiple brands and companies that produce this equipment, they have not found any that can meet the specific needs of the Boise VA Medical Center. [REDACTED]

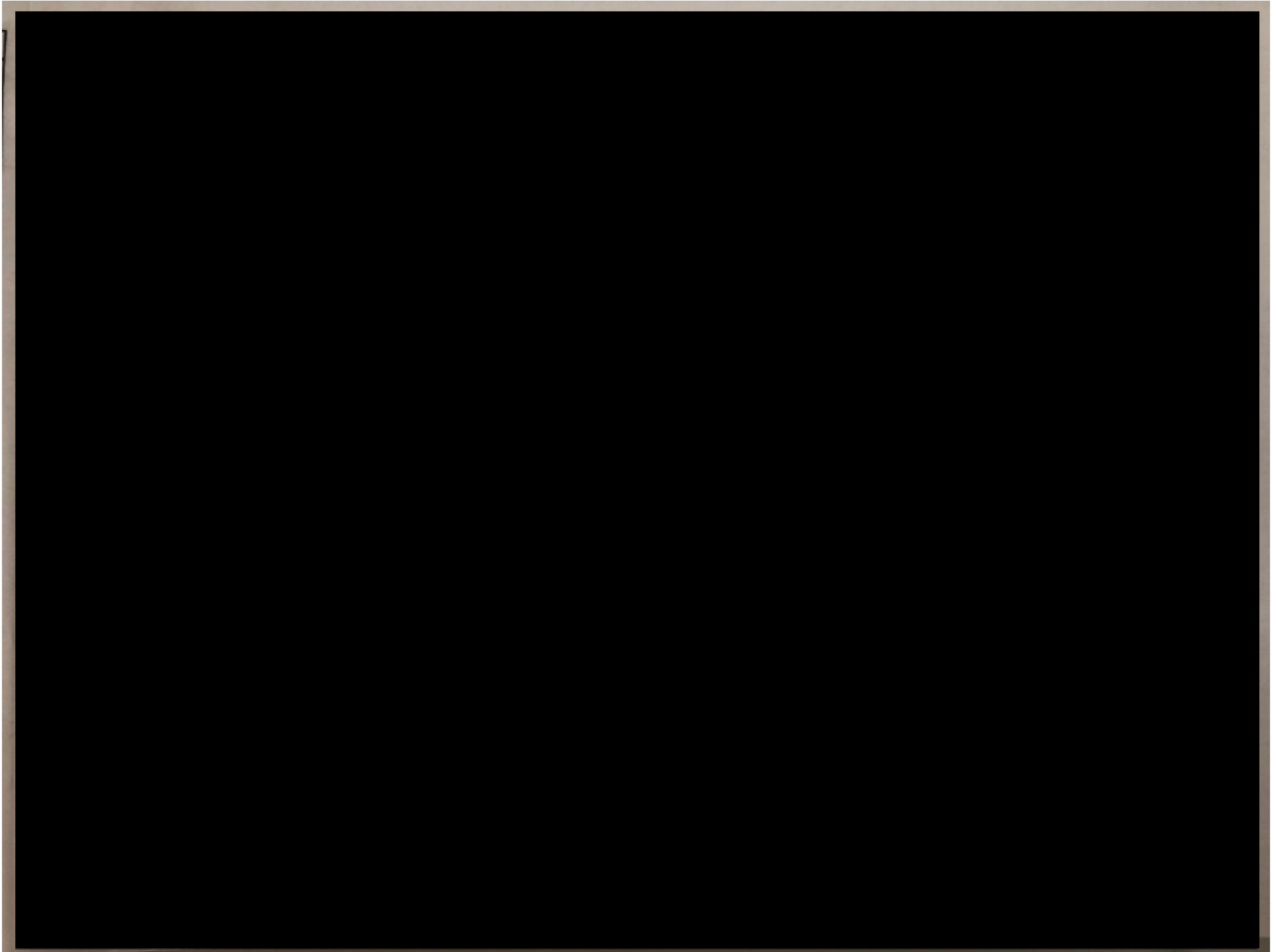
[REDACTED]  
[REDACTED]  
[REDACTED]. Since our IHC workload is relatively small, a smaller/compact instrument would be the best fit for us. It is more cost effective, with lower cost of initial buying and maintenance. A bigger equipment will require redesign of the laboratory space, and therefore not practical or cost effective to the VA. The Leica equipment will fit in the existing space available at the medical center and prevent any re-design or constructions costs as well as make this piece of equipment functional to the group upon delivery and installation. Additionally, the smaller instrument produces less hazardous waste generated, which will save staff time and space to store hazardous waste in the laboratory and in the GEMS shed. [REDACTED]  
[REDACTED]

[REDACTED]

Another major factor/consideration in choosing the right instrument, is an open system. The VA requires the most open system available in order to accommodate both clinical and research needs. The more open an automated IHC instrument, the more flexibility of developing customized IHC protocols, including choosing primary and secondary antibodies, and application in different tissue samples. In addition, Boise VA research department wants to collaborate with clinical lab in using automated IHC instrument. [REDACTED]

[REDACTED]

[REDACTED]



Part of our research included the analysis of a scientific article that compared 9 different IHC automatic stainer [REDACTED]

**First Criterion:**

Boise VAMC Anatomic Pathology laboratory is looking for a fully automated walkaway IHC stainer from dewaxing to counter staining.

**IHC Platforms that failed the first criterion:**

- 1- Biocare Medical IntelliPath FLX: no slide baking, no dewaxing capability, no on-board heating.
- 2- Dako Auto stainer Link 48: no slide baking, separate module for dewaxing capability, separate module for on board heating. The separate modules will have extra cost and will need more laboratory space to place them. Also, these different modules will require more hand on tech time. Resulting in a semi-automated system and not fully automated.

3- **Termo Scientific Lab Vision Autostainer:** no slide baking, separate module for dewaxing capability, separate module for on board heating. The separate modules will have extra cost and will need more laboratory space to place them. Also, these different modules will require more hand on tech time. Resulting in a semi-automated system and not fully automated.

4- **Dako Omnis-** No slide baking

**Second Criterion:**

Boise VAMC Anatomic Pathology Laboratory is looking for an automated IHC stainer that can accept other vendor's reagents (Open system).

**IHC Platforms that failed the second criterion:**

1- **Celerus Diagnostics Wave RPD:** only accepts primary antibodies from other vendors.

2- **Ventana Bench Mark XT:** only accepts primary antibodies from other vendors.

3- **Ventana Bench Mark Ultra:** only accepts primary antibodies from other vendors.

**Third Criterion:**

Boise VAMC Anatomic Pathology Laboratory is looking for an automated IHC stainer that is small and can fit in our available space without having to spend time and money in construction to redesign the laboratory to accommodate the equipment.

Here is a picture of the laboratory area that is available for the IHC instrument: the table measurements are 59 ½ (W) x 30 (D) x 32 (H) in inches.



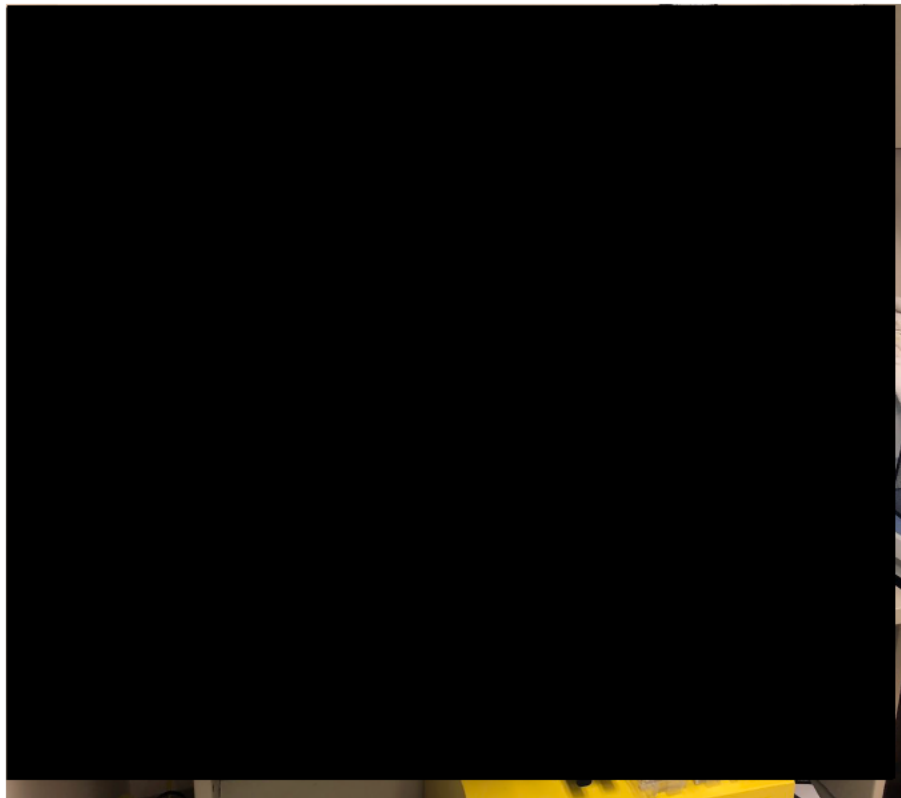
**IHC Platform that failed the third criterion:**

1- **Leica Bond-III:** When comparing Bond-III (53.5 (W) x 31 (D) x 31 (H) in inches) and Bond-Max (30 (W) x 30.5 (D) x 28 (H) in inches) we prefer Bond-Max because the size of Bond-III will not be

optimal for our available counter space. If the table is removed to accommodate Bond-III (Floor model) there will not be space for the computer and the label printer.

In conclusion, after all the platforms documented in the scientific paper were evaluated following the Boise VAMC requirements for an optimal IHC slide stainer the equipment of choice is BOND-MAX from Leica Biosystems.

To further make sure this is the optimal IHC equipment for our laboratory [REDACTED] [REDACTED] space, stain quality, automation, maintenance and hazardous waste amount for disposal.



During a period of a month this stainer was tested and 190 slides were stained and it only produced approximately 1 gallon of hazardous waste (\$48.31 per month) due to the fact that this equipment has the capability to separate non-hazardous waste from the hazardous waste.

Once this equipment was set up to run, the tech could walk away and come back to it when the stains were done.

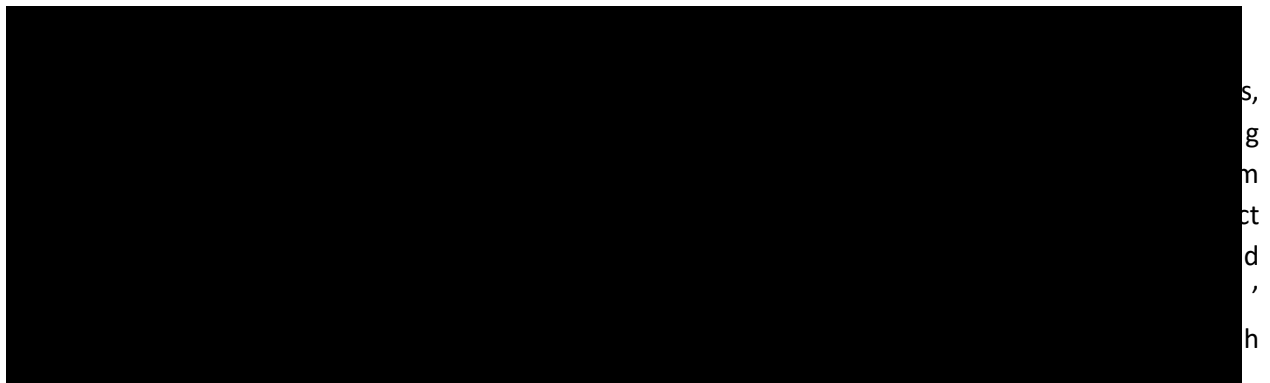
The routine maintenance was minimal with not significant down time or adjustment of personnel:

- Daily maintenance was performed in less than 10 min.
- Weekly preventative maintenance was performed in less than 15 min.
- Monthly preventative maintenance didn't required decontamination and it was performed in less than 30 min.

The following are some highlights of the unique features of Leica.

**Unique Characteristics for Leica Bond-Max that no other automated stainer have:**

- Leica BOND- MAX IHC stainer can produce 30 stained slides in 3.5 hours per run with continuous additional slide loading capability.
- Leica BOND-MAX can run 3 different detection systems simultaneously including ISH with capacity for 36 different reagents per run which increases the operational flexibility of the lab.
- Leica BOND-MAX utilizes patented Covertile technology which allows for minimal (150ul) reagent usage per slide, maintains individual slide humidity, and delivers unprecedented tissue retention on the patient slide resulting in fewer re-cuts and repeats.



**Leica Bond-Max dimensions (30 (W) x 30.5 (D) x 28 (H) in inches)**

As a major contributing factor to the product required by the requesting station, the dimensions need to be equal to or less than the Leica Bond Max, or a construction project could likely be required to expand the available space within the laboratory to accommodate for only several inches of greater dimensions seen in other products. This potential cost is completely avoided by selecting the Leica Bond

Max product. Additionally, the Leica Bond Max [REDACTED]  
[REDACTED]  
[REDACTED]

Immunohistochemical stains/testing (IHC) are very important for anatomic pathology practice. The advantages of the IHC stainer are standardization of IHC testing, faster turnaround time and more accurate pathological diagnosis which results in better patient care. Because of this, patient life expectancy and quality of life after particular diagnosis can be expected to be extended and improved due to earlier treatment.

**Technique(s) used to conduct market research:**

- Scientific literature review
- Discussion with end users (Histopathology technician and Anatomic Pathology Supervisor from DOD and VAMC Anatomic Pathology Laboratories)
- Review of the IHC stainers manuals, catalog, brochures (Leica Biosystems Bond-Max and Ventana Medical System's Benchmark XT)
- Tested a Leica Bond-Max demo in the laboratory
- Current histopathology technician in charge of the IHC project has previous work experience with Leica Bond-Max

**Questions used in our market research:**

- Can you tell me what are the top two things you like about the equipment and the least two things you do not like about the equipment?
- Overall, how do you find the IHC stainer to perform?
- What are the benefits of an open system vs a closed system?
- Can you please describe the customer service you have received?
- How much service time or down time have you experienced with the equipment?
- What is your average turn-around time for your IHC stains?
- What is your opinion on the ease of use?
- Are the pathologists satisfied with the quality of stains?
- What were your impressions of the training you received from the manufacturer?
- What other information would you like to share with us about the IHC stainer?
- Can you describe what maintenance needs to be performed on the equipment and how long it takes your techs to perform?

Leica Biosystems, Biocare Medical, Celerus Diagnostics, Dako, Roche Ventana Medical System, and Thermo Scientific were identified during our literature review as the companies that offer an IHC automated stainer [REDACTED]

**Laboratory Projected workload and Maintenance goals:**

Our current IHC workload is approximately 20-40 IHC stains per week, which is considered a small workload and therefore a smaller instrument will work best for our laboratory. A smaller instrument will be less expensive to purchase and maintain (service, reagents, and waste disposal). In addition, less maintenance relieves staff hours allowing greater focus on other areas of responsibility within the anatomic pathology laboratory, which in turn will result in an increase of workflow efficiency.

**Open vs Closed systems:**

Generally, there are two types of automated IHC open and closed system. The closed system or semi open systems limit the use of antibodies, reagents and detection system. The limitation of the closed system will not allow the use of the instrument for research or laboratory developed IHC test to further optimize IHC stains panels for which in turns will aid the pathologist in reaching an accurate diagnosis. To have the flexibility to accommodate the needs of laboratory developed protocols for personalize medicine in the Anatomical Pathology Laboratory and the needs of the research department, we will need an open system that can accept any vendor's reagents.

[REDACTED]

[REDACTED] The Bond-Max fits perfect in our countertop available space, the instrument was easy to operate and had very minimal daily, weekly and monthly maintenance. Our current reference lab where we send out all our IHC tests use Ventana and the Pathologist were able to compare the slides from Bond-Max [REDACTED] and they were satisfied with the quality of the Bond-Max IHC stainer. [REDACTED]

**Maintenance time and Cost:**

For maintenance [REDACTED]

[REDACTED] the instrument will not be operational during the maintenance of the equipment, therefore once per month the turn-around time of the IHC stains will be affected which will delay the patient treatment. Also, we currently only have two histopathology technician and every time the maintenance must be conducted a contract fee basis histopathology technician will have to come to cover the other duties of grossing and cytology processing while the fully staffed



histopathology technician focusses on the maintenance of the equipment. Every time we have a fee basis histopathology technician [REDACTED] the Bond-Max that only takes 30 min of hand on tech time which will cost the lab \$10.90.

**Hazardous waste Calculations and Cost:**

[REDACTED] Leica Bond-Max 190 slides were stained and the amount of hazardous waste generated was approximately 1 gallon in 1 month (20ml hazardous waste per slide). [REDACTED] hazardous waste per slide therefore if we stain 190 slides with this equipment it will generate approximately 8 gallons of hazardous waste in 1 month. According to GEMS coordinator (attached e-mail) 5 gallons of hazardous waste will cost [REDACTED] (per 5 months of hazardous waste) and 15 gallons of hazardous waste will cost [REDACTED] (per 1 3/4 month of hazardous waste). The GEMS coordinator indicated that they don't have the facility to store the amount of waste generated by [REDACTED].

**Possible Revenue:**

Bond-Max, which is an open system IHC stainer, will allow the Anatomic Pathology laboratory to provide IHC service to the research department with the potential to generate revenue that can offset some of the cost of the equipment and the reagents.

**Patient Care Cost Reduction:**

The importance of acquiring an IHC automated instruments is to run IHC test in house which will help pathologists give more definitive/accurate diagnosis, faster turn-around time and better patient care. The pathologist will have the final diagnosis report available for the clinical team faster if the IHC is run in house vs send it out to a reference laboratory. The faster the clinical team have the pathology report the faster they can coordinate a treatment plan, which\* will shorten the patient stay in the hospital and will potentially save the cost involved in an inpatient care.

**5. Contracting Officer's Certification:** *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

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Michael J. Allred  
Branch Chief, Supply 2  
NCO 20

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Date