County of Albany Department of General Services – Purchasing Division Sole Source Justification

A sole source procu	plicy, Section IV: rement is justified when there is e vendor who can provide the g	s only one good or service	ements that can reasonably meet the need
Department:I	Health		
Contact Name:	Shanna Witherspoon		
Phone #:518-44	7-4584		
Requisition #:			
Describe in detail th	e products and/or services to be	procured:	
COVID-19 school to	esting for the K-12 schools in A	lbany County.	

Detail how this/ these produce(s) meet(s) your needs. Define the unique benefits to the County of the item as compared to other products in the marketplace. Show that no other product provides substantially equivalent or similar benefits and that, considering the benefits received, the cost of the item is reasonable in comparison to other products in the marketplace. (Attach a separate page if needed)

A sole source determination has been decided based on the following criteria.

- FDA EUA or Approved saliva-based, qPCR screening and diagnostic testing for SARS-COV-2; FDA authorization or approval to pool up to 12 specimens and ability to perform reflex testing without needing to obtain an additional patient specimen; test must be highly sensitive (LOD of 1,000cp/ml or less as measured by the FDA Reference Panel).
 - o https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-eme
- CLIA/CLEP certified with appropriate authorizations for COVID-19 testing; pooled testing results available within 24 hours of specimen receipt by the lab, reflex results available in 12-24 hours thereafter.
- Data Requirements:
- On-line patient registration (inclusive of all necessary consent and HIPAA waiver documents); clinical screening and diagnostic results delivered to patients electronically; individual results delivered electronically to organizations (i.e. schools, municipalities, etc.) and in a format that may be downloaded; results delivered electronically to NYSDOH.
- Training and Customer Service:
- o Training materials and remote support provided to organizations to facilitate patient registrations and efficient on-site specimen collections; specimen collection devices delivered to organizations within 2 business days of request; overnight UPS shipping labels available on request and provided at cost; on-site support

available upon request and provided at cost.

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• Ability to sequence positive specimens to facilitate SARS-COV-2 phylogenetic tracking.

Vendor Name:	_Quadrant Biosciences
Vendor Address:	505 Irving Avenue, Suite 3100 A-B
Phone: Fax:	315-614-2325
Product Needed by da	.te:
Estimated Total Dolla	rs for this procurement: \$3,000,000
Funding Source: Albas	ny County awarded contract from HRI per Centers for Disease Control and Prevention

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	iled explanation of Vendor Sole Source Status, i.e., what is the basis for your identifying this ole source? Check any that apply.
	The vendor is the manufacturer of the product and has no distributors. (Attach manufacturer's letter as documentation.)
	The vendor is the only reseller of the manufacturer's product in this geographic region. (Attach manufacturer's letter as documentation.)
	Item to be purchased is a supply for equipment which is under warranty, and use of any product other than specified will void the warranty. (Attach copy of warranty with such requirement highlighted).
	Item is proprietary and is additional product or software which must work with an existing system. (Provide letter of documentation from system manufacturer.)
	Product has been standardized for use in Albany County through the Albany County legislative process. (Attach copy of Resolution.)
X	Other (Provide a statement on a separate page with detailed documentation.)
Department I	Head or Designee: Shama Witherson, Assistant Com. of Finance
	Signature: Sharo White Exp





July 22, 2021

Albany County, Department of Health Shanna Witherspoon 175 Green Street Albany, NY 12202

To Whom it May Concern:

This letter is to confirm that the Clarifi COVID-19 Saliva Test is a sole source product sold and distributed exclusively by Quadrant Biosciences Inc. No division of Quadrant Biosciences, nor any other company, makes a similar or competing product. This product must be purchased directly from Quadrant Biosciences at the following address:

Quadrant Biosciences
505 Irving Avenue Suite 3100 A-B
Syracuse, NY 13210
315-614-2325

NY Vendor ID: 1100146168

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- Data Requirements:
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delivered electronically to NYSDOH.

- Training and Customer Service:
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- Additional Services:
 - Ability to sequence positive specimens to facilitate SARS-COV-2 phylogenetic tracking.

There is no other like product available for purchase that would serve all of the following: FDA authorization, pooling capacity, and saliva collection type.

If you desire additional information on the Clarify COVID-19 testing service offered by Quadrant, visit Quadrant's website at www.quadrantbiosciences.com or schools.quadrantbiosciences.com.

Certified By:	
Signature Date	
Signature of:	
Title:	
Agency Approval by:	
Signature Date	
Name and Title	
Company Representative Acknowledgmer	nt
Signature:	

Name and Title: H. Brady Millican, EVP Sales