

Posting Date: August 4, 2022

Closing Date: August 14, 11:30 a.m. ET

Reference Number: 22-045436

To: NCI Bid Board

From: Tanika Crossen
NCI CCR Procurement, Program Analyst
crossent@nih.gov

Subject: NCI Bid Board Posting – to purchase FISH Probes for miFISH application

Among the defining concepts of the Genetics Branch (GB) is one that underlies its basic research focus and others that form the foundation of its clinical and translational research activities. The concept that underlies basic research is that cancer is a genetic disease caused by genetic instability. That instability is a function of all the inherited and acquired effects that mediate plasticity and alterability at the level of DNA. The success of molecular genetics over the past two decades has been the identification of genes involved in pathways of growth and development, and the identification of the mechanisms by which the normal regulation and/or products of these genes are altered in cancer. The elucidation of the necessary and sufficient factors that govern genetic instability, the description of the common and disparate themes among different types of instability, and the cataloging of distinct patterns of gene expression in tumors compared to the normal tissues from which they arise are within the purview and distinct perspective of this branch. There is, in addition, a clinical/translational mantle that this branch is called upon to shoulder.

GB developed a multiplex interphase Fluorescence in situ hybridization (miFISH) analysis to investigate tumor clonality and heterogeneity. The lab is able to determine copy numbers for up to 35 different genes within the same nucleus by multiplexing multicolor FISH probe panels. This complex approach is crucially dependent on custom-made probes that are produced according to our specifications (sequence, concentration, dyes), show an excellent signal-to-noise ratio and work reliably and consistently over a spectrum of different cell and patient tissue materials.

miFISH assay is unique in the sense that when combined five differentially labeled FISH probes in one panel according to assay driven hybridization schemes. GB then multiplex up to 7 different 5-color probe panels by repeated hybridizations and relocations of the same nuclei via a custom program on a Bioview scanner. This complex approach is dependent on reliable custom-made gene probes according to our sequence specifications, labeled with highly specific dye nucleotides and furthermore, very concentrated probes are needed so that GB can mix five different probes per custom panel with sufficient signal intensity for each of the probes.

The National Cancer Institute plans to purchase a FISH Probes for miFISH application from Empire Genomics, Buffalo, NY to perform this work. This is not a request for competitive quotation. However, if any interested party believes it can meet the attached requirements, it may submit a statement of capabilities. The capability statement must be in writing and must

contain information and material in sufficient detail to allow NCI to determine if the party can fully meet this requirement. The capability statement must be received in the contracting office by 11:30 AM on August 14, 2022 ET. A determination by the Government not to compete this requirement based upon responses to this notice is solely within the discretion of the Government. Information received will be considered solely for the purpose of determining whether to conduct a competitive procurement.

Sole Source Justification:

GB developed a multiplex interphase Fluorescence in situ hybridization (miFISH) analysis to investigate tumor clonality and heterogeneity. GB is able to determine copy numbers for up to 35 different genes within the same nucleus by multiplexing multicolor FISH probe panels. This complex approach is dependent on custom-made probes that are produced according to our specifications (sequence, concentration, dyes) by the company Empire Genomics. No other company can provide customized probes that work reliably for our miFISH approach.

Attached Documents:

SF18

Statement of Need

FAR Clause 52.213-4 Simplified Acquisitions Terms and Conditions (AUG 2020) is applicable and available in full text upon request

REQUEST FOR QUOTATION (THIS IS NOT AN ORDER)		THIS RFQ <input type="checkbox"/> IS <input checked="" type="checkbox"/> IS NOT A SMALL BUSINESS SET-ASIDE		PAGE OF PAGES 1 1	
1. REQUEST NO. 22-045436	2. DATE ISSUED 8/4/2022	3. REQUISITION/PURCHASE REQUEST NO.	4. CERT. FOR NAT. DEF. UNDER BDSA REG. 2 AND/OR DMS REG. 1	RATING	
5a. ISSUED BY NCI CCR Purchasing Administrative Resource Center			6. DELIVER BY (Date)		
5b. FOR INFORMATION CALL (NO COLLECT CALLS)			7. DELIVERY <input checked="" type="checkbox"/> FOB DESTINATION <input type="checkbox"/> OTHER (See Schedule)		
NAME Tanika Crossen, Program Analyst		TELEPHONE NUMBER AREA CODE NUMBER 301 480-0602		9. DESTINATION	
8. TO:			NIH, NCI		
a. NAME		b. COMPANY Empire Genomics	b. STREET ADDRESS		
c. STREET ADDRESS			c. CITY Bethesda		
d.. CITY		e.. STATE	f.. ZIP CODE	d.. STATE MD	e. ZIP CODE 20892
10. PLEASE FURNISH QUOTATIONS TO THE ISSUING OFFICE IN BLOCK 5a ON OR BEFORE CLOSE OF BUSINESS (Date) 8/14/22 11:30 EST		IMPORTANT: This is a request for information, and quotations furnished are not offers. If you are unable to quote, please indicate on this form and return it to the address in Block 5a. This request does not commit the Government to pay any costs incurred in the preparation of the submission of this quotation or to contract for supplies or services. Supplies are of domestic origin unless otherwise indicated by quoter. Any representations and/or certifications attached to this Request for Quotations must be completed by the quoter.			
11. SCHEDULE (Include applicable Federal, State and local taxes)					
ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)
	FISH Probes for miFISH application Notice of Intent: If submitting a capability statement, please e-mail only 1 copy of the technical capability statement to Tanika Crossen @ crossent.mail.nih.gov See attached statement of work This will be awarded as a Firm-Fixed Price Contract.				
12. DISCOUNT FOR PROMPT PAYMENT		a. 10 CALENDAR DAYS (%)	b. 20 CALENDAR DAYS (%)	c. 30 CALENDAR DAYS (%)	d.. CALENDAR DAYS NUMBER PERCENTAGE
NOTE: Additional provisions and representations <input type="checkbox"/> are <input type="checkbox"/> are not attached.					
13. NAME AND ADDRESS OF QUOTER			14. SIGNATURE OF PERSON AUTHORIZED TO SIGN QUOTATION		15. DATE OF QUOTATION
a. NAME OF QUOTER			16. SIGNER		b. TELEPHONE AREA CODE
b. STREET ADDRESS					
c. COUNTY			a. NAME (Type or print)		NUMBER
d. CITY		e. STATE	f. ZIP CODE	c. TITLE (Type or print)	

STATEMENT OF NEED (SON)

1.0 TITLE

Empire Genomics FISH Probes for miFISH application

2.0 BACKGROUND

Our lab developed a multiplex interphase Fluorescence in situ hybridization (miFISH) analysis to investigate tumor clonality and heterogeneity. We are able to determine copy numbers for up to 35 different genes within the same nucleus by multiplexing multicolor FISH probe panels. This complex approach is crucially dependent on custom-made probes that are produced according to our specifications (sequence, concentration, dyes), show an excellent signal-to-noise ratio and work reliably and consistently over a spectrum of different cell and patient tissue materials.

3.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

4.0 SPECIAL ORDER REQUIREMENTS

Not applicable

4.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS

Our miFISH assay is unique in the sense that we combine five differentially labeled FISH probes in one panel according to assay driven hybridization schemes. We then multiplex up to 7 different 5-color probe panels by repeated hybridizations and relocations of the same nuclei via a custom program on a Bioview scanner. This complex approach is dependent on reliable custom-made gene probes according to our sequence specifications, labeled with highly specific dye nucleotides and furthermore, very concentrated probes are needed so that we can mix five different probes per custom panel with sufficient signal intensity for each of the probes.

We therefore contacted two prominent custom FISH probe companies. Both companies provided us with custom test probes manufactured according to our specifications (sequence, dyes compatible with our filter sets, and concentration of probes). The Empire Genomics probes were clean with low background and delivered consistently good and reproducible hybridization results for our probe panels even in difficult formalin-fixed, paraffin-embedded (FFPE) patient material. On the other hand, we frequently experienced unacceptable high background with the Cytotest probes with variable hybridization results which makes them unsuitable for our application.

STATEMENT OF NEED (SON)

miFISH analysis can only be done successfully with concentrated, strong, clean and reliable custom probes according to our specifications. Empire Genomics probes fulfill these requirements.

The following product features/characteristics are required for this requirement:

- **Custom probes according to our sequence requirements**
- **Probes have to be labeled with fluorescent dyes according to our specifications**
- **Probe concentrations have to be adjusted to allow mixing of five differentially labeled FISH probes in one panel**
- **Signal intensity needs to be very high to work in difficult patient materials like archival FFPE tumor tissues**
- **Background needs to be very low to guarantee good signal to noise ratio of the probes in difficult patient materials**
- **Probes need to work reliably in a variety of different materials, from cell lines to fresh, frozen and archival patient material**

4.2 DELIVERY / INSTALLATION

Delivery should be made to the following address:

NIH/NCI
Ried lab
50 South Drive
Building 50, Rm. 1408
Bethesda, MD 20892
Attn: Kerstin Heselmeyer, Dara Wangsa

Items shall be delivered within 6-12 months of purchase order award.

4.3 TRAINING

Not applicable

52.213-4 Terms and Conditions-Simplified Acquisitions (Other Than Commercial Items).

As prescribed in [13.302-5\(d\)](#), insert the following clause:

TERMS AND CONDITIONS-SIMPLIFIED ACQUISITIONS (OTHER THAN COMMERCIAL ITEMS) (AUG 2020)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses that are incorporated by reference:

(1) The clauses listed below implement provisions of law or Executive order:

(i) [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (JAN 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(ii) [52.204-23](#), Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (JUL 2018) (Section 1634 of Pub. L. 115-91).

(iii) [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (AUG 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(iv) [52.222-3](#), Convict Labor (JUN 2003) (E.O.11755).

(v) [52.222-21](#), Prohibition of Segregated Facilities (APR 2015).

(vi) [52.222-26](#), Equal Opportunity (*Sept* 2016) (E.O.11246).

(vii) [52.225-13](#), Restrictions on Certain Foreign Purchases (Jun 2008) (E.O.s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).

(viii) [52.233-3](#), Protest After Award (AUG 1996) ([31 U.S.C.3553](#)).

(ix) [52.233-4](#), Applicable Law for Breach of Contract Claim (OCT 2004) (Pub.L.108-77, 108-78 ([19 U.S.C. 3805 note](#))).

(2) Listed below are additional clauses that apply:

(i) [52.232-1](#), Payments (APR 1984).

(ii) [52.232-8](#), Discounts for Prompt Payment (FEB 2002).

(iii) [52.232-11](#), Extras (APR 1984).

(iv) [52.232-25](#), Prompt Payment (JAN 2017) .

(v) [52.232-39](#), Unenforceability of Unauthorized Obligations (JUN 2013).

(vi) [52.232-40](#), Providing Accelerated Payments to Small Business Subcontractors (DEC 2013).

(vii) [52.233-1](#), Disputes (MAY 2014).

(viii) [52.244-6](#), Subcontracts for Commercial Items (AUG 2020).

(ix) [52.253-1](#), Computer Generated Forms (JAN 1991).

(b) The Contractor shall comply with the following FAR clauses, incorporated by reference, unless the circumstances do not apply:

(1) The clauses listed below implement provisions of law or Executive order:

(i) [52.204-10](#), Reporting Executive Compensation and First-Tier Subcontract Awards (JUN 2020)(Pub. L. 109-282) ([31 U.S.C. 6101 note](#)) (Applies to contracts valued at or above the threshold specified in FAR [4.1403](#)(a) on the date of award of this contract).

(ii) [52.222-19](#), Child Labor-Cooperation with Authorities and Remedies (JAN 2020) (E.O.13126) (Applies to contracts for supplies exceeding the micro-purchase threshold, as defined in FAR [2.101](#) on the date of award of this contract).

(iii) [for Materials, Supplies, Articles, and Equipment](#), Contracts for Materials, Supplies, Articles, and Equipment (JUN 2020) ([41 U.S.C.chapter 65](#)) (Applies to supply contracts over the threshold specified in FAR [22.602](#) on the date of award of this contract, in the United States, Puerto Rico, or the U.S. Virgin Islands).

(iv) [52.222-35](#), Equal Opportunity for Veterans (JUN 2020) ([38 U.S.C.4212](#)) (Applies to contracts valued at or above the threshold specified in FAR [22.1303](#)(a) on the date of award of this contract).

(v) [52.222-36](#), Equal Employment for Workers with Disabilities (JUN 2020) ([29 U.S.C.793](#)) (Applies to contracts over the threshold specified in FAR [22.1408](#)(a) on the date of award of this contract, unless the work is to be performed outside the United States by employees recruited outside the United States). (For purposes of this clause, "United States" includes the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.)

(vi) [52.222-37](#), Employment Reports on Veterans (JUN 2020) ([38 U.S.C.4212](#)) (Applies to contracts valued at or above the threshold specified in FAR [22.1303](#)(a) on the date of award of this contract).

(vii) [52.222-41](#), Service Contract Labor Standards (AUG 2018) ([41 U.S.C.chapter 67](#)) (Applies to service contracts over \$2,500 that are subject to the Service Contract Labor Standards statute and will be performed in the United States, District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, Johnston Island, Wake Island, or the outer Continental Shelf).

(viii)

(A) [52.222-50](#), Combating Trafficking in Persons (JAN 2019) ([22 U.S.C. chapter78](#) and E.O 13627) (Applies to all solicitations and contracts).

(B) Alternate I (MAR 2015) (Applies if the Contracting Officer has filled in the following information with regard to applicable directives or notices: Document title(s), source for obtaining document(s), and contract performance location outside the United States to which the document applies).

(ix) [52.222-55](#), Minimum Wages Under Executive Order 13658 (DEC 2015) (Applies when [52.222-6](#) or [52.222-41](#) are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia)).

(x) [52.222-62](#), Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706) (Applies when [52.222-6](#) or [52.222-41](#) are in the contract and performance in whole or in part is in the United States (the 50 States and the District of Columbia).)

(xi) [52.223-5](#), Pollution Prevention and Right-to-Know Information (MAY 2011) (E.O. 13423) (Applies to services performed on Federal facilities).

(xii) [52.223-11](#), Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693)(applies to contracts for products as prescribed at FAR [23.804](#)(a)(1)).

(xiii) [52.223-12](#), Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693) (Applies to maintenance, service, repair, or disposal of refrigeration equipment and air conditioners).

(xiv) [52.223-15](#), Energy Efficiency in Energy-Consuming Products (DEC 2007) ([42 U.S.C. 8259b](#)) (Unless exempt pursuant to [23.204](#), applies to contracts when energy-consuming products listed in the ENERGY STAR® Program or Federal Energy Management Program (FEMP)) will be-

(A) Delivered;

(B) Acquired by the Contractor for use in performing services at a Federally-controlled facility;

(C) Furnished by the Contractor for use by the Government; or

(D) Specified in the design of a building or work, or incorporated during its construction, renovation, or maintenance).

(xv) [52.223-20](#), Aerosols (JUN 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons as a propellant or as a solvent; or contracts for maintenance or repair of electronic or mechanical devices).

(xvi) [52.223-21](#), Foams (JUN 2016) (E.O. 13693) (Applies to contracts for products that may contain high global warming potential hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons as a foam blowing agent; or contracts for construction of buildings or facilities).

(xvii) [52.225-1](#), Buy American-Supplies (MAY 2014) ([41 U.S.C. chapter 67](#)) (Applies to contracts for supplies, and to contracts for services involving the furnishing of supplies, for use in the United States or its outlying areas, if the value of the supply contract or supply portion of a service contract exceeds the micro-purchase threshold, as defined in FAR [2.101](#) on the date of award of this contract, and the acquisition-

(A) Is set aside for small business concerns; or

(B) Cannot be set aside for small business concerns (see [19.502-2](#)), and does not exceed \$25,000).

(xviii) [Excess Food Donation to Nonprofit Organizations](#), Promoting Excess Food Donation to Nonprofit Organizations (JUN 2020) ([42 U.S.C. 1792](#)) (Applies to contracts greater than the threshold specified in FAR [26.404](#) on the date of award of this contract, that provide for the provision, the service, or the sale of food in the United States).

(xix) [52.232-33](#), Payment by Electronic Funds Transfer-System for Award Management (OCT 2013) (Applies when the payment will be made by electronic funds transfer (EFT) and the payment office uses the System for Award Management (SAM) as its source of EFT information).

(xx) [52.232-34](#), Payment by Electronic Funds Transfer-Other than System for Award Management (JUL 2013) (Applies when the payment will be made by EFT and the payment office does not use the SAM database as its source of EFT information).

(xxi) [52.247-64](#), Preference for Privately Owned U.S.-Flag Commercial Vessels (FEB 2006) ([46 U.S.C.App.1241](#)) (Applies to supplies transported by ocean vessels (except for the types of subcontracts listed at [47.504\(d\)](#))).

(2) Listed below are additional clauses that may apply:

(i) [52.204-21](#), Basic Safeguarding of Covered Contractor Information Systems (JUN 2016) (Applies to contracts when the contractor or a subcontractor at any tier may have Federal contract information residing in or transiting through its information system.

(ii) [52.209-6](#), Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment (JUN 2020) (Applies to contracts over the threshold specified in FAR [9.405-2\(b\)](#) on the date of award of this contract).

(iii) [52.211-17](#), Delivery of Excess Quantities (*Sept* 1989) (Applies to fixed-price supplies).

(iv) [52.247-29](#), F.o.b. Origin (FEB 2006) (Applies to supplies if delivery is f.o.b. origin).

(v) [52.247-34](#), F.o.b. Destination (NOV 1991) (Applies to supplies if delivery is f.o.b. destination).

(c) FAR [52.252-2](#), *Clauses Incorporated by Reference (Feb 1998)*. This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

[Insert one or more Internet addresses]

(d) *Inspection/Acceptance.* The Contractor shall tender for acceptance only those items that conform to the requirements of this contract. The Government reserves the right to inspect or test any supplies or services that have been tendered for acceptance. The Government may require repair or replacement of nonconforming supplies or reperformance of nonconforming services at no increase in contract price. The Government must exercise its postacceptance rights-

(1) Within a reasonable period of time after the defect was discovered or should have been discovered; and

(2) Before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

(e) *Excusable delays.* The Contractor shall be liable for default unless nonperformance is caused by an occurrence beyond the reasonable control of the Contractor and without its fault or negligence, such as acts of God or the public enemy, acts of the Government in either its sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, unusually severe weather, and delays of common carriers. The Contractor shall notify the Contracting Officer in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the Contracting Officer of the cessation of such occurrence.

(f) *Termination for the Government's convenience.* The Government reserves the right to terminate this contract, or any part hereof, for its sole convenience. In the event of such termination, the Contractor shall immediately stop all work hereunder and shall immediately cause any and all of its suppliers and subcontractors to cease work. Subject to the terms of this contract, the Contractor shall be paid a percentage of the contract price reflecting the percentage of the work performed prior to the notice of termination, plus reasonable charges that the Contractor can demonstrate to the satisfaction of the Government, using its standard record keeping system, have resulted from the termination. The Contractor shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit the Contractor's records. The Contractor shall not be paid for any work performed or costs incurred that reasonably could have been avoided.

(g) *Termination for cause.* The Government may terminate this contract, or any part hereof, for cause in the event of any default by the Contractor, or if the Contractor fails to comply with any contract terms and conditions, or fails to provide the Government, upon request, with adequate assurances of future performance. In the event of termination for cause, the Government shall not be liable to the Contractor for any amount for supplies or services not accepted, and the Contractor shall be liable to the Government for any and all rights and remedies provided by law. If it is determined that the Government improperly terminated this contract for default, such termination shall be deemed a termination for convenience.

(h) *Warranty.* The Contractor warrants and implies that the items delivered hereunder are merchantable and fit for use for the particular purpose described in this contract.

(End of clause)