

Bid Analysis Spreadsheet-3-09

No.	Bidder	<i>RFP</i> 1.0	<i>RFP</i> 2.0	<i>RFP</i> 4.0	<i>RFP</i> 5.0	<i>RFP</i> 6.0	<i>RFP</i> 7.0	<i>RFP</i> 3.0	Details
		<i>Cell Bank</i>	<i>Ad Source</i>	<i>Ad VB</i>	<i>Ad Purified</i>	<i>Vialing</i>	<i>Repository</i>	<i>Services</i>	
1	Texcell (Institut Pasteur, France)							X	Ad titration (TCID50)
1	Texcell (Institut Pasteur, France)							X	AAV PCR
1	Texcell (Institut Pasteur, France)							X	RCA Bioassay
1	Texcell (Institut Pasteur, France)							X	PCR for human pathogens (EBV, HIV1, HIV2, HTLV1, HTLV2, HBV, HCV, CMV, Parvo B19, AAV
1	Texcell (Institut Pasteur, France)							X	Mycoplasma 21CFR610.30
1	Texcell (Institut Pasteur, France)							X	Bovine Contamin. BPyV, BVDV PCR
1	Texcell (Institut Pasteur, France)							X	Porcine Contam. PCR
1	Texcell (Institut Pasteur, France)							X	Bovine Viruses, BT cell Bioassay
1	Texcell (Institut Pasteur, France)							X	Porcine Viruses Bioassay
2	EM Processing (Gibbstown, NJ)							X	Benzonase endonuclease
3	EM Processing (Gibbstown, NJ)							X	Fractogel EMD resins (anion exchange)
4	Life Technologies							X	Reagents, cells and / or tissue culture medium up to a value of \$10K
5	Osmonics (Minnetonka, MN)							X	Cell Culture System (for 3 mos); agreement to be signed
6	ATCC (Manassas, VA)							X	Inventory management of Ad5WT Ref Mat & advertisement of its availability on ATCC website (if not chosen as repository)
7	Crucell (Leiden, The Netherlands)	X							PER.C6; 20 x 1 mL WCB vials; CofA. **Crucell reqs. Institution rec'g have lic agreement in place or agree to destroy remaining cell materials post-manufacture.

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8	Univ Alabama @ Birmingham (Birmingham, AL)	X							293 cells WCB, 100 x 1 mL vials. CofA.
9	Canji (San Diego, CA)		X						Ad 5WT lysate, plaque-purified material. Char & history info. Sterility, mycoplasma, AAV neg. Identity confirmed by RFLP. Test methods described for PN, IU, ID. 3 x 10 mL vials @ 5.29E11 p/mL; 5.07 e9 IU/mL donation.
10	Crucell (Leiden, The Netherlands)		X						Plasmid donation which can be grown on PER.C6 cells. 2 Plasmids req'd. Only in conjunction with MVB production on PER.C6 cell line & Crucell reqs. PER.C6 cell line agreement in place with institution using cells. Plasmid maps. Endotoxin & sequencing pending acceptance of bid.
11	Univ Alabama @ Birmingham (Birmingham, AL)		X						Purified Ad5WT Virus material. Char & history info. Sterility, mycoplasma neg. Identity confirmed by PCR. Test method descriptions not included. 1 x 30 mL vial @ 1.6e10 pfu/mL donation.
12	Canji (San Diego, CA)			X					Microcarrier bioreactor culture production of Lysate VB proposed. 10 mL fill into PETG bottles; frozen. CofA. Test methods described. Description of facilities/capability. CGMP.
13	Crucell (Leiden, The Netherlands)			X					Production of Lysate VB using PER.C6 system only. Bioreactor serum-free prodxn method. 100 x 1 mL vials #@ 5E11 vp @ in 1.8 mL Nunc cryovials; frozen storage. CofA. Description of facilities/capability. CGMP.
14	Introgen Therapeutics (Houston, TX)			X					Flat stock culture, Lysate VB proposed Glass vials 3 mL w/crimp grey butyl stopper closure. CofA. Test methods described. Description of facilities/capability. CGMP.

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15	Univ Alabama @ Birmingham (Birmingham, AL)			X					Flat stock culture, CsCl purified VB proposed in Tris pH 8.0, MgCl, 5% sucrose, 0.5 mL vials. CofA. No test methods provided. Description of facilities/capability. GLP.
16	Canji (San Diego, CA)				X				Microcarrier bioreactor culture production, Chromatographic purification. Proposed formulation of Tris, Phosphate, MgCl, pH 7.5, 10% Glycerol, 2% Sucrose w/supporting data. Fill bulk into 14 x 200 mL fill PETG bottles. Frozen. Cof A. Test methods described. Description of facilities/capability. CGMP.
17	Crucell (Leiden, The Netherlands) & Selective Genetics (San Diego, CA)				X				Production only using PER.C6 cell line via CGMP using serum-free bioreactor method. Chromatography purification. Proposed formulation of Tris, pH 8.0, 2.5% Glycerol, 25 mM NaCl w/supporting data. Bulk fill into EVA bags w/c-flex tubing for sterile connections. Frozen for shipping for vialing. Shipping proposed at 2-8C just prior to fill within 48 hrs upon receipt. Not respons for import permits to vialing location. CofA. No test methods. Description of facilities/capability. CGMP.
18	Introgen Therapeutics (Houston, TX) & Selective Genetics (San Diego, CA)				X				Flat stock culture (CellCube), Chromatographic purification. Proposed formulation of Tris, pH 8.0, 2.5% Glycerol, 25 mM NaCl w/supporting data. Est. 50-60 x 50 mL polypropylene tubes. Frozen. Cof A. Test methods described. Description of facilities/capability. CGMP.
19	Selective Genetics (San Diego, CA)				X				Proposed formulation of Tris, pH 8.0, 2.5% Glycerol, 25 mM NaCl with supporting data package & description of test methods used. Supplied in conjunction with RFP 5.0 bids from Introgen & Crucell.

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20	ATCC (Manassas, VA)					X			1.0 mL Nunc vials CatNo366656. Filling staged @ 0.5 L dispensed manually with repeater pipettes over 1 hr into 1000 vials @ 0.5 mL each in BSC. 1-2 working days for 4-5 L. Bulk & vials to be kept cold & stirring during operation. @ Fill to receive a different batch no. in blocks of approx 500. Quick freeze in vapor phase Liq N2 unless otherwise instructed. Freezer -70C storage. Preliminary TCID50 of vial material @ ATCC included. Other tests included: sterility, mycoplasma.
21	Introgen Therapeutics (Houston, TX)					X			Filling in 10K cleanroom w/ CI 100 BSC. Prodt thaw then 4C ON, held @ RT during fill. Fill manually using dispensing pump in 3-4 runs of 1500 vials/run on sep days. Qual run included. Std EM. Container - glass 3mL w/ grey butyl stopper crimped closure proposed. CofA. Test methods provided. Description of facilities/capability. CGMP.
22	NIBSC (So. Mimms, England)					X			Filling in Cat.3 lab suite. Fill via Robotic module in BSC. Fill from a single container continuously over 8 hrs for 4500-5000 x 0.5 mL fill. Decon of vials; then freezing via controlled rampdown temp machine. Containers proposed Sartstedt 2 mL vials with screw cap & o-ring, OR 5 mL glass w/silicon stopper & crimp, OR 4 mL Nalgene plastic screw tops. Exper'd with filling & shipping. Questions who to pay for shipping. Sterility test included (10 vials). Testing facilities accredited for batch release by UKAS; production facilities ISO 9001 certified.

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23	ATCC (Manassas, VA)						X		Capacity available for freezer storage of 5000 Ref Mat vials & 50+ VB vials, plus 15 x 1 mL CB (LN). Plan to split locations into @ least 2 freezer locations @ facility. Freezers & LN alarmed. Backup generator. Secure storage. CGMP storage capability available. Propose \$162/vial. Propose to monitor distribution of initial 500 vials with limits to orders @ 10 vials/order. Provide 1 yr notification for new lot. Indefinite storage capability. IATA & import/export lic permit exper'd. Routinely ship 145K specimens/yr in 44K shipments w/established distribution partners in Eur, Jap, & So. Korea.
24	MDS PharmaServices (Bothell, WA - formerly MDS Panlabs)						X		Sep vials into 6 Freezers -86C. LN for CB vials. Alarmed/monitored Freezer & LN. Backup power. Propose \$225/vial plus actual shipping cost. Estimated US shipping \$50; Internat'l shipping \$400. Packaging for shipping \$20. Propose to limit 4 vials @ \$225 @; may purchase up to add'l 6 vials @ \$1500. \$1275 of premium will set aside (via Ad Ref Mat Wkg Grp) for offset of costs of producing next lot or another purpose. Purchaser accounts limited to 10 vials. Modification pending tracking of 1st lot distribution. IATA & import/export lic permit exper'd. Min 5 yr repository commitment.

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25	NIBSC (So. Mimms, England)						X		Freezer capacity for Ad Ref Mat. ISO 9001 certified for proc/ label/ storing/ pkging/ &shipping ref mats. IATA & import/export lic permit exper'd. Approx 62K shipmts/yr. Described current charge structure (L40 for UK; \$75 for non-UK; EU recips add'l VAT @ 17.5%. Recips pay for shipping. Limit to 4 vials/requester per 6 mo with tracking to limit 8 vials/yr. Per ARMWG will distribute vials to grps involved in char/phase. Cost of add'l freezer to be covered?? Willing to partner with another selected repository service to make distribution easier & more cost effective (ie, partners in US, Eur and far east).
26	Qbiogene (Montreal, Canada)						X		Propose storage/distribut via Carlsbad/CA-US & Strasbourg/Fr facilities. @ location storage in 2 freezers -80C. MCB in LN. Use heat-sealed cryogenic bags for shipment of Ad on dry ice. Freezers & LN alarmed. Secure storage. IATA & import/export lic permit exper'd. Approx 75K shipmts/yr. Propose cost of \$218/vial to cover costs & establish replenishment fund (\$50/vial). Restriction of vials per account per yr. Max number to be established via tracking system. Min 5 yr repository commitment.