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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)									DATE February 1999	
BUDGET ACTIVITY 5 - Engineering and Manufacturing Development				PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development						
COST (In Thousands)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	4200	5299	9705	9448	9386	11917	10490	10695	Continuing	Continuing
D812 Military Human Immunodeficiency Virus (HIV) Vaccine and Drug-Engineering Development	0	282	2372	3249	3659	3606	1719	1912	Continuing	Continuing
D832 Combat Medical Materiel-Engineering Development	2198	2415	3395	2248	3178	3334	3537	3532	Continuing	Continuing
D834 Soldier System Protection-Engineering Development	873	867	685	690	890	1560	1847	1847	Continuing	Continuing
D849 Infectious Disease Drug and Vaccine-Engineering Development	1129	1735	3253	3261	1659	3417	3387	3404	Continuing	Continuing

A. Mission Description and Budget Item Justification: This engineering and manufacturing development program funds: (1) improved medical equipment and drugs essential to counteracting lethal and human performance degrading effects of infectious diseases, and (2) medical equipment essential to meeting medical requirements on the integrated battlefield, with emphasis on decreased size, weight and high mobility, yet supporting large numbers of combat casualties. Additionally, foreign medical materiel may be procured for exploitation of advanced technology and development to meet Army medical defense goals. This program element supports the full-scale development of vaccines, prophylactic and therapeutic drugs, resuscitation fluids and drug products for Acquired Immune Deficiency Syndrome (AIDS). This program funds engineering and manufacturing development for both large and small combat casualty care end items for location of casualty, diagnosis, rapid intensive care delivery, intensive care evacuation platforms, and rapidly mobile, lightweight surgical facilities and equipment. Additionally, the program element funds engineering and manufacturing development of medical equipment that provides protection against physiological, psychological or environmental factors that degrade physical performance. This includes engineering development of vision corrective devices for protective masks. This program is primarily managed by the U.S. Army Medical Research and Materiel Command.

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B. Program Change Summary	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget (FY 1999 PB)	4345	5338	7264	8011
Appropriated Value	4483	5338		
Adjustments to Appropriated Value				
a. Congressional General Reductions	-138	-39		
b. SBIR / STTR	-109			
c. Omnibus or Other Above Threshold Adjustments	-36			
d. Below Threshold Reprogramming				
e. Rescissions				
Adjustments to Budget Years Since <u>FY 1999</u> PB			2441	1437
Current Budget Submit (<u>FY 2000 / 2001</u> PB)	4200	5299	9705	9448

Change Summary Explanation: FY2000/2001 – Funding increased to begin the advanced development on far-forward medical diagnostic kits and accelerate the development of products used to prevent or treat militarily relevant infectious diseases.

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development				PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development				PROJECT D812		
<i>COST (In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D812 Military Human Immunodeficiency Virus (HIV) Vaccine and Drug-Engineering Development	0	282	2372	3249	3659	3606	1719	1912	Continuing	Continuing
<p>A. <u>Mission Description and Justification:</u> This project funds Congressionally mandated, militarily relevant HIV medical countermeasures. This provides for engineering and manufacturing development of sufficient candidate vaccines and drugs to permit large-scale field testing and education/training materials. Efforts are directed to answer militarily unique needs affecting manning, mobilization and deployment. The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD.</p> <p>FY 1998 Accomplishments: Project not funded in FY 1998.</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 275 Provide regulatory affairs support for New Drug Application submission of GP120 recombinant protein HIV vaccine. • 7 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 282</p> <p>FY 2000 Planned Program:</p> <ul style="list-style-type: none"> • 2372 Expand Phase 2/3 efficacy field trials for GP120 recombinant protein HIV vaccine. <p>Total 2372</p> <p>FY 2001 Planned Program:</p> <ul style="list-style-type: none"> • 3249 Continue expanded Phase 2/3 efficacy field trials for GP120 recombinant protein HIV vaccine. <p>Total 3249</p> <p>B. <u>Other Program Funding Summary:</u> Not applicable.</p> <p>C. <u>Acquisition Strategy:</u> Test and evaluate commercially developed vaccine candidates in government-managed trials.</p> <p>D. <u>Schedule Profile:</u> Not applicable.</p>										
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ARMY RDT&E COST ANALYSIS (R-3)										DATE February 1999		
BUDGET ACTIVITY 5 - Engineering and Manufacturing Development					PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development					PROJECT D812		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No individual product/contacting cost grater than \$1 million		WRAIR/AFRIMS		282		2372		3249		Continue	Continue	
Subtotal Product Development:				282		2372		3249		Continue	Continue	
<p>II. Support Costs: None</p> <p>III. Test and Evaluation: None</p> <p>IV. Management Services: None</p>												
Project Total Cost:				282		2372		3249		Continue	Continue	

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ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								DATE February 1999		
BUDGET ACTIVITY 5 - Engineering and Manufacturing Development				PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development					PROJECT D832	
<i>COST (In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D832 Combat Medical Materiel-Engineering Development	2198	2415	3395	2248	3178	3334	3537	3532	Continuing	Continuing
<p>A. <u>Mission Description and Justification:</u> The project supports engineering and manufacturing development to field new and improved medical materiel essential for combat casualty care to reduce the logistical support requirements and minimize loss. The major contract is United Defense Technologies, San Jose, CA.</p> <p>FY 1998 Accomplishments:</p> <ul style="list-style-type: none"> • 200 Conducted Patient Movement Item (field gurney) testing at military laboratories. • 1889 Built Armored Medical Evacuation Vehicle (AMEV) prototype. Finished final design and testing of Armored Medical Treatment Vehicle (AMTV). • 83 Completed final evaluation of Hypertonic Saline Dextran. • 26 Built Special Operations Surgical Table that is sturdy, lightweight and capable of being broken down for transport. <p>Total 2198</p> <p>FY 1999 Planned Program:</p> <ul style="list-style-type: none"> • 99 Complete final evaluation of Patient Movement Item. • 258 Begin initial operational test and evaluation (IOT&E) of initial version of Life Support for Trauma and Transport (LSTAT). • 1995 Participate in National Training Center (NTC) rotation, conduct concept experimentation program test (CEPT) and incorporate test recommendation in redesign of AMEV. • 63 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs <p>Total 2415</p> <p>FY 2000 Planned Program:</p> <ul style="list-style-type: none"> • 491 Conduct technology cost-benefit trade-off analysis and initiate formal acquisition program for upgraded LSTAT device. • 1204 Conduct a production qualification test (PQT) and begin low rate initial production (LRIP) for the AMEV. • 1000 Conduct clinical trials for the fibrin bandage program and prepare the Product License Application (PLA) and Establishment License Application (ELA). • 700 Conduct clinical trials and continue development of the Food and Drug Administration (FDA) submission of thawed blood processing system. <p>Total 3395</p>										
Project D832			Page 5 of 15 Pages				Exhibit R-2A (PE 0604807A)			

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development	PROJECT D832
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FY 2001 Planned Program:

- 1000 Continue IOT&E of initial version of LSTAT.
- 118 Conduct clinical trials on next generation jet injector.
- 50 Prepare IOT&E and conduct Milestone II/III In-process Review (IPR) for Warrior Medic program.
- 1080 Conduct Milestone III for AMEV.

Total 2248

B. Other Program Funding Summary: Not applicable.

C. Acquisition Strategy: Evaluate commercially developed materiel in government-managed trials.

D. <u>Schedule Profile</u>	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
AMEV - MSIII						4Q01				
LSTAT - MSII							4Q02			

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development	PROJECT D832
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I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. AMEV	MIPR	PM Bradley, Warren MI	1938	2051	Nov 98	1204	Nov 99	1780	Nov 00	Continue	Continue	
b. LSTAT	TBD	TBD				2191	Nov 99					
Subtotal Product Development:			1938	2051		3395		1780		Continue	Continue	

II. Support Costs: No product/contract costs greater than \$1M individually

III. Test and Evaluation: No product/contract costs greater than \$1M individually

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			260	364				468		Continue	Continue	
Subtotal Management Services:			260	364				468		Continue	Continue	

Project Total Cost:			2198	2415		3395		2248		Continue	Continue	
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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development	PROJECT D834
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COST <i>(In Thousands)</i>	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D834 Soldier System Protection-Engineering Development	873	867	685	690	890	1560	1847	1847	Continuing	Continuing

A. Mission Description and Justification: This project supports engineering development of preventive medicine materiel, including devices, pharmacologicals and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions. Focus is on reduction in the incidence of personnel losses due to preventable disease and nonbattle injuries through development of environmental and physiological performance monitors and other preventive medicine countermeasures. A major contractor is Stanford Research Institute, Palo Alto, CA.

FY 1998 Accomplishments:

- 198 Supported training and maintenance effort for Corps Warfighter Exercise.
 - 199 Planned and built external interface options to Composite Health Care System (CHCS), the Theater Army Medical Management Information System (TAMMIS), and the Defense Blood Standard System (DBSS).
 - 238 Provided system engineering support for hardware infrastructure for the Theater Medical Information Program (TMIP) early user test.
 - 238 Provided system engineering support for system integration with the Combat Service Support Control System (CSSCS) and the Global Combat Support System (GCSS).
- Total 873

FY 1999 Planned Program:

- 633 Provide system engineering support for system integration with the Force XXI Battle Command - Brigade and Below (FBCB2) and GCSS.
 - 211 Provide hardware infrastructure support for TMIP block 1 initial operational test and evaluation (IOT&E).
 - 23 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs
- Total 867

FY 2000 Planned Program:

- 255 Provide integration support for TMIP block 2 IOT&E.
 - 296 Prepare for Phase 2/3 clinical trial and regulatory affairs support for secondary indication for modafinil to counter warfighter fatigue.
 - 134 Prepare New Drug Application (NDA) supplement for filing with the Food and Drug Administration (FDA) on second indication for modafinil.
- Total 685

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development	PROJECT D834
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FY 2001 Planned Program:

- 259 Provide integration support for TMIP block 3 IOT&E.
 - 184 Provide initial manufacture support of leishmania skin test antigen (LSTA) kits for Phase 2 clinical trials.
 - 247 Continue program and regulatory affairs support for secondary indication for modafinil to counter warfighter fatigue.
- Total 690

C. Acquisition Strategy: Test and evaluate in-house and commercially developed vaccine candidates in government-managed trials to meet FDA requirements.

D. Schedule Profile	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
TMIP block 1 - MS III				3Q99						
TMIP block 1 infrastructure support - MS III				3Q99						
TMIP block 2 - MS III					3Q00					
TMIP block 2 infrastructure support - MS III					3Q00					
TMIP block 3 - MS III						3Q01				
TMIP block 3 infrastructure support - MS III						3Q01				

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ARMY RDT&E COST ANALYSIS (R-3)										DATE February 1999		
BUDGET ACTIVITY 5 - Engineering and Manufacturing Development					PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development					PROJECT D834		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
c. No product/contract costs greater than \$1M individually			674	649		296		372		Continue	Continue	
Subtotal Product Development:			674	649		296		372		Continue	Continue	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually						134		59		Continue	Continue	
Subtotal Support Costs:						134		59		Continue	Continue	
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			199	218						Continue	Continue	
Subtotal Test and Evaluation:			199	218						Continue	Continue	

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development					PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development					PROJECT D834		
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
b. No product/contract costs greater than \$1M individually						255		259		Continue	Continue	
Subtotal Management Services:						255		259		Continue	Continue	
Project Total Cost:			873	867		685		690		Continue	Continue	

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development	PROJECT D849
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COST (<i>In Thousands</i>)	FY1998 Actual	FY 1999 Estimate	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D849 Infectious Disease Drug and Vaccine-Engineering Development	1129	1735	3253	3261	1659	3417	3387	3404	Continuing	Continuing

A. Mission Description and Justification: This project funds engineering and manufacturing development of sufficient candidate medical countermeasures to permit large-scale field testing and complete studies required for Food and Drug Administration (FDA) licensure. Work performed in laboratories and among troop populations is directed to prevention, diagnosis, and treatment of viral, bacterial and parasitic diseases to prevent casualties, sustain operational performance and minimize deaths and disability of armed forces during military operations.

Acquisition Strategy: Test and evaluate in-house and commercially developed vaccine candidates in government-managed trials to meet FDA requirements.

FY 1998 Accomplishments:

- 457 Completed Phase 2 challenge study of Campylobacter vaccine.
- 672 Completed Phase 2 clinical trial in Egyptian children of Enterotoxigenic *Eschericha coli* (ETEC) vaccine.
- Total 1129

FY 1999 Planned Program:

- 475 Conduct full-scale expanded Phase 3 field trials to evaluate efficacy of antimalarial drug WR238605.
- 283 Conduct Phase 3 treatment study of antimalarial drug WR238605.
- 260 Conduct Phase 2/3 proof of concept field trial of Campylobacter vaccine.
- 80 Conduct Phase 1 safety trial of new adjuvant lot of Campylobacter vaccine.
- 365 Conduct Phase 3 study in Egyptian infants and children of ETEC vaccine.
- 244 Conduct Phase 3 pivotal trial in Israel of ETEC vaccine.
- 28 Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR) Programs
- Total 1735

FY 2000 Planned Program:

- 488 Complete Phase 3 long-term prophylaxis study in Kenya of antimalarial drug WR238605.
- 487 Complete Phase 3 clinical trials for long-term prophylaxis study of antimalarial drug WR238605 with the French military.

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development	PROJECT D849
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- 409 Complete Phase 3 treatment study of antimalarial drug WR238605.

FY 2000 Planned Program: (continued)

- 78 Provide regulatory affairs support for New Drug Application submission of antimalarial drug WR238605.
 - 199 Complete Phase 2/3 proof of concept field trial of Campylobacter vaccine.
 - 199 Complete Phase 1 safety trial of new adjuvant lot of Campylobacter vaccine.
 - 597 Initiate Phase 3 pivotal trial of Campylobacter vaccine.
 - 398 Continue Phase 3 study in Egyptian infants and children of ETEC vaccine.
 - 398 Continue Phase 3 pivotal trial in Israel of ETEC vaccine.
- Total 3253

FY 2001 Planned Program:

- 688 Complete Phase 3 study in Egyptian infants and children of ETEC vaccine.
 - 690 Complete Phase 3 pivotal trial in Israel of ETEC vaccine.
 - 685 Complete Phase 3 pivotal trial of Campylobacter vaccine.
 - 798 Initiate Phase 2/3 trials for Leishmania skin test antigen.
 - 200 Initiate Phase 3 trials for licensure of malaria rapid diagnostic device.
 - 200 Provide regulatory affairs support for licensure of malaria rapid diagnostic device.
- Total 3261

B. Other Program Funding Summary: Not Applicable.

C. Acquisition Strategy: Test and evaluate in-house and commercially developed vaccine candidates in government-managed trials to meet FDA requirements.

D. Schedule Profile	<u>FY 1996</u>	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	<u>FY 2000</u>	<u>FY 2001</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Leishmania skin test - MS III							4Q02			
Camouflage face paint - MS II/III						3Q01				
WR238605 antimalarial - MS III							1Q02			
Dengue rapid diagnostic device - MS III									1Q04	
Paromomycin antileishmanial - MS III								4Q03		
ETEC vaccine - MS III									1Q04	

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ARMY RDT&E COST ANALYSIS (R-3)											DATE February 1999	
BUDGET ACTIVITY 5 - Engineering and Manufacturing Development				PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development						PROJECT D849		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			43									
Subtotal Product Development:			43									
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			29	52		98		98		Continue	Continue	
Subtotal Support Costs:			29	52		98		98		Continue	Continue	
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			677	1075		2017		2021		Continue	Continue	
Subtotal Test and Evaluation:			677	1075		2017		2021		Continue	Continue	

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BUDGET ACTIVITY 5 - Engineering and Manufacturing Development	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development	PROJECT D849
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IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a. No product/contract costs greater than \$1M individually			380	608		1138		1142		Continue	Continue	
Subtotal Management Services:			380	608		1138		1142		Continue	Continue	
Project Total Cost:			1129	1735		3253		3261				

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