

**CLINIC INFORMATION**

Name: **Smith Wellness Center**  
Address: **1234 Main Road**  
**Suite 56**  
**Memphis, TN 38018**  
Fax:  
Provider: **Dr. Ronald J. Smith**

**PATIENT INFORMATION**

Name: **Sunimul, John**  
DOB: **12/25/1964**  
Gender: **M**  
ID: **M978654**

**SPECIMEN INFORMATION**

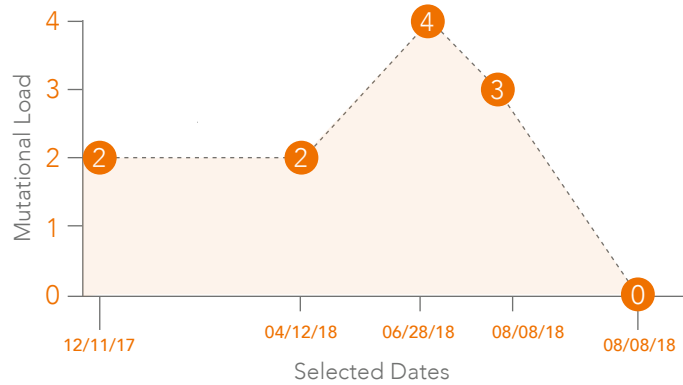
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Run Date: **5/11/2018 2:27 PM**  
Date Reported: **5/12/2018**

SPECIMEN ID: **0064381239** TEST INDICATION: **COLORECTAL CANCER**

**SUMMARY OF RESULTS**

Gene(s) Tested:	<b>50</b>
Alteration(s) Detected:	<b>0</b>
FDA-Approved Targeted Therapies	<b>2</b>
Additional Therapies	<b>0</b>
Open Clinical Trials (see page 6 for details)	<b>44</b>

**MUTATIONAL TRENDING** (for detailed Test History, see pg. 3)



These mutations, relevant in Colorectal Cancer, were tested for and determined to be absent:

- BRAF V600 mutation (Not Found)
- KRAS codons 12, 13, 59, 61, 117 or 146 (Not Found)
- KRAS codons 12, 13, 59, 61, 117 or 146 (Not Found)

The following 50 Genes were tested:

- ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, EZH2, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, JAK2, JAK3, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53, VHL,

**IMMUNOTHERAPY TEST RESULTS**

FDA GUIDANCE

PD-L1 EXPRESSION **POSITIVE (>50%)** Nivolumab, Pembrolizumab indicated  
MSI-H **NOT DETECTED**

**ALTERATIONS DETECTED**

GENE	ALTERATION	MUTANT FRACTION	FDA TARGETED THERAPIES (Colorectal Cancer)	FDA TARGETED THERAPIES (For Other Indications)	CLINICAL TRIALS (Details Below)
<b>KRAS</b>	No Reported Mutation	-	Cetuximab, Panitumumab		<b>31</b>
<b>NRAS</b>	No Reported Mutation	-	Cetuximab, Panitumumab		<b>14</b>
<b>BRAF</b>	No Reported Mutation	-	None	Melanoma (BRAF Wild Type): Nivolumab & Pembrolizumab Indicated; Dabrafenib, Trmetinib, Vemurafenib & Cobimetinib NOT indicated	<b>24</b>

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\*This test detects the presence of pathogen and must be evaluated with clinical symptoms to diagnose disease. All test established and validated by Laboratory and not FDA approved. Standards for validation exceed FDA requirements.

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## LABEL INFORMATION for FDA-APPROVED THERAPEUTICS

### Cetuximab in Colorectal Cancer

**KRAS** *FDA Referenced Subgroup: EGFR protein expression positive, KRAS Wild-type*  
Cetuximab is indicated for the treatment of K-Ras wild-type, epidermal growth factor receptor (EGFR)-expressing, metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use. Cetuximab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either K-Ras or N-Ras. Cetuximab is not indicated for treatment of Ras-mutant colorectal cancer or when the results of the Ras mutation tests are unknown

*FDA Referenced Subgroup: KRAS codon 12 and 13 mutation negative*  
Cetuximab is indicated for KRAS wild-type, EGFR-expressing, metastatic colorectal cancer as determined by FDA-approved tests. Cetuximab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either K-Ras or N-Ras. Cetuximab is not indicated for treatment of Ras-mutant colorectal cancer or when the results of the Ras mutation tests are unknown

**NRAS** *FDA Referenced Subgroup: EGFR protein expression positive, KRAS Wild-type*  
Cetuximab is indicated for the treatment of K-Ras wild-type, epidermal growth factor receptor (EGFR)-expressing, metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use. Cetuximab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either K-Ras or N-Ras. Cetuximab is not indicated for treatment of Ras-mutant colorectal cancer or when the results of the Ras mutation tests are unknown

*FDA Referenced Subgroup: KRAS codon 12 and 13 mutation negative*  
Cetuximab is indicated for the treatment of K-Ras wild-type, epidermal growth factor receptor (EGFR)-expressing, metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use. Cetuximab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either K-Ras or N-Ras. Cetuximab is not indicated for treatment of Ras-mutant colorectal cancer or when the results of the Ras mutation tests are unknown

### Panitumumab in Colorectal Cancer

**KRAS** *FDA Referenced Subgroup: KRAS codon 12 and 13 mutation negative*  
Panitumumab is indicated for the treatment of wild-type KRAS metastatic colorectal cancer as determined by an FDA-approved test. Panitumumab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either KRAS or NRAS

**NRAS** *FDA Referenced Subgroup: NRAS codon 12 and 13 mutation negative*  
Panitumumab is indicated for the treatment of wild-type KRAS metastatic colorectal cancer as determined by an FDA-approved test. Panitumumab is not indicated for the treatment of patients with colorectal cancer that harbor somatic mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either KRAS or NRAS

*The Information compiled in this report is from the FDA's Table of Pharmacogenomic Biomarkers in Drug Labeling, augmented with information extracted from the drug label at the FDA. The list does not represent a listing of all drugs that might be approved for the indication, but only those drugs approved for the specific biomarker, indication and referenced subgroup.*

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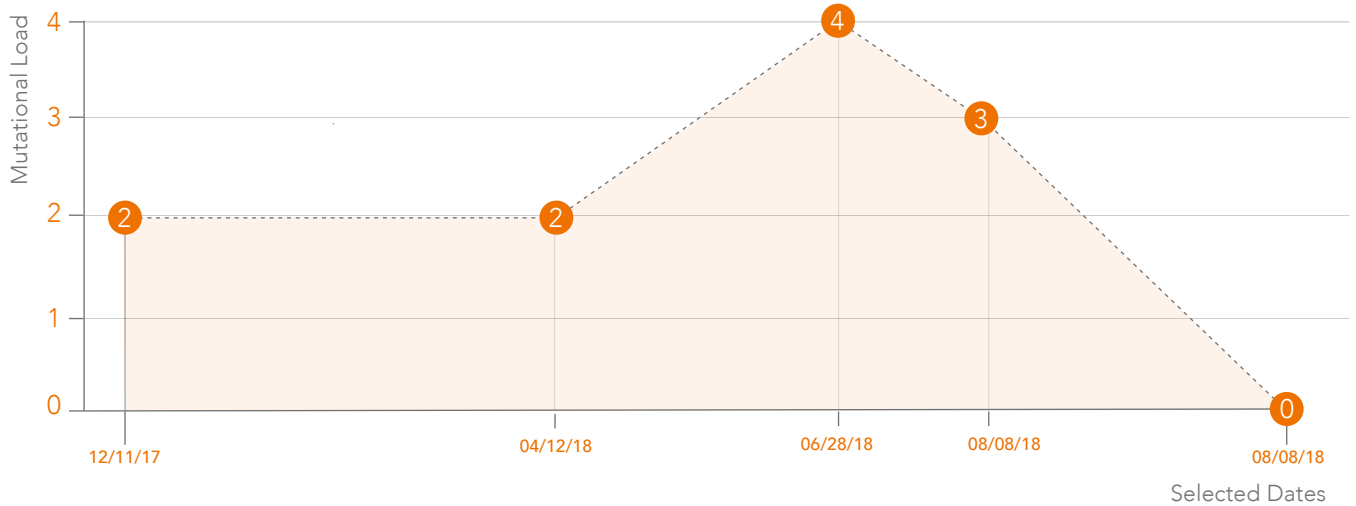
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**MUTATIONAL TRENDING**



**TEST HISTORY** NUMBER OF TESTS: **6** | Most Recent: November, 1 2018 | Earliest: December 11, 2017

TEST DATE	SAMPLE ID	MUTATION LOAD	GENE	ALTERATION	FREQUENCY
11/1/2018	6438	0			
8/9/2018	5388	3	PIK3CA TP53 VHL	M1040V I232T W117*	6% 2% 3.3%
6/28/2018	5113	4	APC CTNNB1 TP53 TP53	T1313A Q28R c.376-2A>G P72R	5.6% 8.4% 2.8% 96%
4/12/2018	4714	2	TP53 TP53	C238R P72R	16.6% 97.4%
12/11/2017	4135	2	TP53 TP53	G464R P72R	2.3% 92.4%

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TEST HISTORY (CONTINUED)    NUMBER OF TESTS: **6** | Most Recent: November, 1 2018    Earliest: December 11, 2017

TEST DATE	SAMPLE ID	MUTATION LOAD	GENE	ALTERATION	FREQUENCY
12/11/2018	4135	<b>2</b>	BRAF TP53	G464R P72R	2.3% 92.4%

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## DRUGS & DRUG COMBINATIONS USED IN COLORECTAL CANCER

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### DRUGS APPROVED FOR COLORECTAL CANCER

5-Fluorouracil  
Bevacizumab  
Capecitabine  
Cetuximab  
Irinotecan Hydrochloride  
Leucovorin Calcium  
Nivolumab  
Oxaliplatin  
Panitumumab  
Ramucirumab  
Regorafenib  
Trifluridine and Tipiracil Hydrochloride  
Ziv-Aflibercept

The drugs listed above are those approved by the FDA for Colorectal Cancer. This information comes from the lists maintained on the National Cancer Institute (NCI) website ([www.cancer.gov](http://www.cancer.gov)). Each generic drug name here links to summary information at the NCI on the uses of these drugs, research results, possible side effects and approval information.

### DRUG COMBINATIONS USED IN COLORECTAL CANCER

CAPOX  
FOLFIRI  
FOLFIRI-BEVACIZUMAB  
FOLFIRI-CETUXIMBA  
FOLFOX  
FU-LV  
XELIRI  
XELOX

Listed above are common drug combinations used in Colorectal Cancer. They are listed by abbreviation or common name and are shown in capital letters. The individual drugs in the combinations are FDA-approved. The combinations themselves are not usually approved, although they are widely used. This information comes from the lists maintained on the National Cancer Institute (NCI) website ([www.cancer.gov](http://www.cancer.gov)). Each combination name here links to summary information at the NCI and includes the list of drugs that make up the combination and explains what the combination is used for.

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OPEN CLINICAL TRIALS: **44**

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TRIAL ID	GENE(S)	INDICATION(S)	PHASE	STATUS
NCT02906059	<b>BRAF; KRAS; NRAS</b>	<b>Colorectal Cancer</b> Study of Irinotecan and AZD1775, a Selective Wee 1 Inhibitor, in RAS or BRAF Mutated, Second-line Metastatic Colorectal Cancer STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT03087071	<b>BRAF; KRAS; NRAS</b>	<b>Colorectal Cancer</b> Panitumumab in Combination With Trametinib in Cetuximab-Refractory Stage IV Colorectal Cancer STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT03099486	<b>BRAF; KRAS; NRAS</b>	<b>Colorectal Cancer</b> Regorafenib Plus 5-Fluorouracil/Leucovorin Beyond Progression in mCRC STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT03365882	<b>BRAF; KRAS; NRAS</b>	<b>Colorectal Cancer</b> S1613, Trastuzumab and Pertuzumab or Cetuximab and Irinotecan Hydrochloride in Treating Patients With Locally Advanced or Metastatic HER2/Neu Amplified Colorectal Cancer That Cannot Be Removed by Surgery STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT03415126	<b>BRAF; KRAS; NRAS</b>	<b>Colorectal Cancer</b> A Study of ASN007 in Patients With Advanced Solid Tumors STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT10184501	<b>KRAS; NRAS</b>	<b>Colorectal Cancer</b> Panitumumab and Chemotherapy in Patients With Advanced Colorectal Cancer After Prior Therapy With Bevacizumab STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT02079740	<b>KRAS; NRAS</b>	<b>Colorectal Cancer</b> Trametinib and Navitoclax in Treating Patients With Advanced or Metastatic Solid Tumors STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT02292758	<b>KRAS; NRAS</b>	<b>Colorectal Cancer</b> Irinotecan and Cetuximab With or Without Bevacizumab in Treating Patients With RAS Wild-Type Locally Advanced or Metastatic Colorectal Cancer That Cannot Be Removed by Surgery STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT02576665	<b>KRAS; NRAS</b>	<b>Colorectal Cancer</b> A Study of Toca 511, a Retroviral Replicating Vector, Combined With Toca FC in Patients With Solid Tumors or Lymphoma (Toca 6) STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT02599324	<b>KRAS; NRAS</b>	<b>Colorectal Cancer</b> A Study to Evaluate Ibrutinib Combination Therapy in Patients With Selected Gastrointestinal and Genitourinary Tumors STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>

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NCT02713373	<b>KRAS; NRAS</b>	Colorectal Cancer Cetuximab and Pembrolizumab in Treating Patients With Colorectal Cancer That is Metastatic or Cannot Be Removed by Surgery STATE(S)	Phase 1 / Phase 2	Recruiting
NCT03043313	<b>KRAS; NRAS</b>	Colorectal Cancer Tucatinib (ONT-380) and Trastuzumab in Treating Patients With HER2+ Metastatic Colorectal Cancer STATE(S)	Phase 2	Recruiting
NCT03190941	<b>KRAS; NRAS</b>	Colorectal Cancer Administering Peripheral Blood Lymphocytes Transduced With a Murine T-Cell Receptor Recognizing the G12V Variant of Mutated RAS in HLA-A*1101 Patients STATE(S)	Phase 1 / Phase 2	Recruiting
NCT02380443	<b>BRAF; KRAS</b>	Colorectal Cancer Increased Frequency of AlloStim® Immunotherapy Dosing in Combination With Cryoablation in Metastatic Colorectal Cancer STATE(S)	Phase 2	Recruiting
NCT02754856	<b>BRAF; KRAS</b>	Colorectal Cancer Tremelimumab (Anti-CTLA-4) Plus Durvalumab (MEDI4736) (Anti-PD-L1) in the Treatment of Resectable Colorectal Cancer Liver Metastases STATE(S)	Phase 1	Recruiting
NCT02857270	<b>BRAF; NRAS</b>	Colorectal Cancer A Study of LY3214996 Administered Alone or in Combination With Other Agents in Participants With Advanced/Metastatic Cancer STATE(S)	Phase 1	Recruiting
NCT02980029	<b>BRAF; KRAS</b>	Colorectal Cancer TVB 2640 for Resectable Colon Cancer Other Resectable Cancers; a Window Trial. STATE(S)	Phase 1	Recruiting
NCT03146962	<b>BRAF; KRAS</b>	Colorectal Cancer High Dose Vitamin C Intravenous Infusion in Patients With Resectable or Metastatic Solid Tumor Malignancies STATE(S)	Phase 2	Recruiting
NCT03223779	<b>BRAF; KRAS</b>	Colorectal Cancer Study of TAS-102 Plus Radiation Therapy for the Treatment of the Liver in Patients With Hepatic Metastases From Colorectal Cancer STATE(S)	Phase 1 / Phase 2	Recruiting
NCT03428126	<b>BRAF; KRAS</b>	Colorectal Cancer Study of Durvalumab (MEDI4736) (Anti-PD-L1) and Trametinib (MEKi) in MSS Metastatic Colon Cancer STATE(S)	Phase 2	Not Yet Recruiting

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NCT02008383	<b>KRAS</b>	<b>Colorectal Cancer</b> Cabozantinib and Panitumumab to Treat KRAS Wild-Type Metastatic Colorectal Cancer STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT02124148	<b>KRAS</b>	<b>Colorectal Cancer</b> A Study of Prexasertib (LY2606368) With Chemotherapy or Targeted Agents in Participants With Advanced Cancer STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT02232152	<b>KRAS</b>	<b>Colorectal Cancer</b> CPI-613 and Fluorouracil in Treating Patients With Metastatic Colorectal Cancer That Cannot Be Removed by Surgery STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT02316340	<b>KRAS</b>	<b>Colorectal Cancer</b> Vorinostat Plus Hydroxychloroquine Versus Regorafenib in Colorectal Cancer STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT02484404	<b>KRAS</b>	<b>Colorectal Cancer</b> Phase I/II Study of the Anti-Programmed Death Ligand-1 Antibody MEDI4736 in Combination With Olaparib and/or Cediranib for Advanced Solid Tumors and Advanced or Recurrent Ovarian, Triple Negative Breast, Lung, Prostate and Colorectal Cancers STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT02613650	<b>KRAS</b>	<b>Colorectal Cancer</b> A Trial of mFOLFIRI With MEK162 in Patients With Advanced KRAS Positive Metastatic Colorectal Cancers STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT02646748	<b>KRAS</b>	<b>Colorectal Cancer</b> Pembrolizumab Combined With Itacitinib (INCB039110) and/or Pembrolizumab Combined With INCB050465 in Advanced Solid Tumors STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT02649790	<b>KRAS</b>	<b>Colorectal Cancer</b> Study of the Safety, Tolerability and Efficacy of KPT-8602 in Patients With Relapsed/Refractory Cancer Indications STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT02703571	<b>KRAS</b>	<b>Colorectal Cancer</b> Study of Safety and Efficacy of Ribociclib and Trametinib in Patients With Metastatic or Advanced Solid Tumors STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT02953782	<b>KRAS</b>	<b>Colorectal Cancer</b> Trial of Hu5F9-G4 in Combination With Cetuximab in Patients With Solid Tumors and Advanced Colorectal Cancer STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>

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NCT03206073	<b>KRAS</b>	<b>Colorectal Cancer</b> A Phase I/II Study of Pexa-Vec Oncolytic Virus in Combination With Immune Checkpoint Inhibition in Refractory Colorectal Cancer STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT03263429	<b>KRAS</b>	<b>Colorectal Cancer</b> Novel PET/CT Imaging Biomarkers of CB-839 in Combination With Panitumumab and Irinotecan in Patients With Metastatic and Refractory RAS Wildtype Colorectal Cancer STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT00897429	<b>BRAF</b>	<b>Colorectal Cancer</b> Studying Tissue Samples From Patients With Stage II Colon Cancer Treated on Clinical Trial CLB-9581 STATE(S)	<b>N / A</b>	<b>Recruiting</b>
NCT01037790	<b>BRAF</b>	<b>Colorectal Cancer</b> PHASE II TRIAL OF THE CYCLIN-DEPEDENT KINASE INHIBITOR PD 0332991 IN PATIENTS WITH CANCER STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT01351103	<b>BRAF</b>	<b>Colorectal Cancer</b> A Study of LGK974 in Patients With Malignancies Dependent on Wnt Ligands STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
NCT01876511	<b>BRAF</b>	<b>Colorectal Cancer</b> Phase 2 Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors STATE(S)	<b>Phase 2</b>	<b>Recruiting</b>
NCT02178722	<b>BRAF</b>	<b>Colorectal Cancer</b> A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of Pembrolizumab (MK-3475) in Combination With Epacadostat (INCB024360) in Subjects With Selected Cancers (INCB 24360-202 / MK-3475-037 / KEYNOTE-037/ ECHO-202) STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT02437136	<b>BRAF</b>	<b>Colorectal Cancer</b> Ph1b/2 Dose-Escalation Study of Entinostat With Pembrolizumab in NSCLC With Expansion Cohorts in NSCLC, Melanoma, and Colorectal Cancer STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
NCT0298224	<b>BRAF</b>	<b>Colorectal Cancer</b> Study of Encorafenib + Cetuximab Plus or Minus Binimetinib vs. Irinotecan/Cetuximab or Infusional 5-Fluorouracil (5-FU)/Folinic Acid (FA)/Irinotecan (FOLFIRI)/Cetuximab With a Safety Lead-in of Encorafenib + Binimetinib + Cetuximab in Patients With BRAF V600E-mutant Metastatic Colorectal Cancer STATE(S)	<b>Phase 3</b>	<b>Recruiting</b>
NCT02972034	<b>BRAF</b>	<b>Colorectal Cancer</b> Study of MK-8353 in Combination With Pembrolizumab (MK-3475) in Participants With Advanced Malignancies (MK-8353-013) STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>

Clinic Name: **Smith Wellness Center**

Patient name: **Sunimul, John**

Requisition Number: **978654**

### CLINIC INFORMATION

Name: **Smith Wellness Center**  
Address: **1234 Main Road**  
**Suite 56**  
**Memphis, TN 38018**  
Fax:  
Provider: **Dr. Ronald J. Smith**

### PATIENT INFORMATION

Name: **Sunimul, John**  
DOB: **12/25/1964**  
Gender: **M**  
ID: **M978654**

### SPECIMEN INFORMATION

Requisition Number: **978654**  
Lab Accession Number: **978654**  
Date Collected: **5/10/2018 1:23 PM**  
Date Received by Lab: **5/11/2018**  
Run Date: **5/11/2018 2:27 PM**  
Date Reported: **5/12/2018**

OPEN CLINICAL TRIALS: **44**

SPECIMEN ID:  
**0064381239**

TEST INDICATION:  
**COLORECTAL CANCER**

TRIAL ID	GENE(S)	INDICATION(S)	PHASE	STATUS
<b>NCT03189030</b>	<b>BRAF</b>	<b>Colorectal Cancer</b> Study of Personalized Immunotherapy in Adults With Metastatic Colorectal Cancer STATE(S)	<b>Phase 1</b>	<b>Recruiting</b>
<b>NCT03317119</b>	<b>BRAF</b>	<b>Colorectal Cancer</b> Trametinib and TAS-102 in Treating Patients With Colon or Rectal Cancer That is Advanced, Metastatic, or Cannot Be Removed by Surgery STATE(S)	<b>Phase 1</b>	<b>Not Yet Recruiting</b>
<b>NCT03377361</b>	<b>BRAF</b>	<b>Colorectal Cancer</b> An Investigational Immuno-therapy Study Of Nivolumab In Combination With Trametinib With Or Without Ipilimumab In Patients With Previously Treated Cancer of the Colon or Rectum That Has Spread STATE(S)	<b>Phase 1 / Phase 2</b>	<b>Recruiting</b>
<b>NCT03391232</b>	<b>BRAF</b>	<b>Colorectal Cancer</b> Safety and Immunogenicity of PolyPEPI1018 Vaccine in the Treatment of Metastatic Colorectal Cancer (OBERTO) STATE(S)	<b>Phase 1</b>	<b>Not Yet Recruiting</b>

Clinic Name: **Smith Wellness Center**

Patient name: **Sunimul, John**

Requisition Number: **978654**