

Compatibility Report

"Committed to increasing abilities and enhancing life"

For:
Sally Sample

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Patient: Sally Sample

Doctor: Dr. Doe

Date received: 01/15/2021

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INTRODUCTION -- TESTING CRITERIA AND INTERPRETATION

BASIS OF SERUM COMPATABILITY AND TESTING LIMITATIONS

Biocompatibility testing is an indirect measurement of the reaction between serum proteins and the composition of various medical restorative materials. Medical restorative materials, just like prescription drugs, can have certain side effects or adverse reactions. Some of these reactions are of medical significance, and some are not. One of the objectives of this report is to alert both the patient and their medical practitioner to their patient-specific biocompatibility of the 8000+ medical restorative materials in our database.

The BioComp Labs serum biocompatibility test provides information about the patient's relative serum protein reactivity to the medical restorative material's chemicals, components, and corrosion products that are currently included in our database. Some manufacturers are reluctant to disclose their complete proprietary formulae for materials. In addition, manufacturers may alter their formulation up to 10% without being required to inform consumers or federal agencies. BioComp Labs is continually updating products in our database as changes are made by the manufacturers.

LABORATORY CERTIFICATION

BioComp Laboratories, Inc. is regulated by the Federal Clinical Laboratories Improvement Act (CLIA) and licensed by the state of Colorado. CLIA certification is completed bi-annually to ensure the quality of reagents, instrument standardization, competence of laboratory personnel, and consistency of reporting standards. In addition, all methodologies and standards are continually being reviewed in accordance with current research and regulatory requirements.

STANDARDS OF REACTION LEVELS

The possible outcomes of the BioComp Labs serum biocompatibility test are:

HIGHLY REACTIVE

This level of reaction indicates distinct protein agglutination, as determined by an optical scanner absorption scale, and is highly suggestive that the chemical, component, or corrosive material is detrimental to the patient's serum. At this reaction level, the potential for an adverse patient reaction is high, and the use of these materials is discouraged.

MODERATELY REACTIVE

This level of reaction indicates a measured reactivity which is markedly less than the highly reactive response, but still sufficiently present as determined by the optical scanner. If there are no options present in the least reactive category, then these moderately reactive medical restorative materials could be considered for use based on the medical practitioner's clinical experience and professional judgement.

LEAST REACTIVE

This level of reaction indicates the least amount of reactivity and that the patient's immune system could tolerate exposure to these medical restorative materials with minor to no measurable response.

TEST RESULTS

The results of this serum biocompatibility test are only for the listed patient. This blood serum test is not a universal endorsement of any single product or product component. All sections of this report are dependent upon the limitations and parameters stipulated in the following Interpretation of Results Disclaimer.

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INTRODUCTION -- TESTING CRITERIA AND INTERPRETATION

INTERPRETATION OF RESULTS DISCLAIMER

BioComp Laboratories, Inc. is not a clinical diagnostic laboratory and cannot provide a diagnosis for immune reactions, disease and/or subsequent treatment. These results are derived from protein agglutination testing that indirectly indicate the biocompatibility between a restorative medical material and the specific patient's serum. The highly reactive, moderately reactive, and least reactive sensitivity outcomes are determined by protein agglutination reactions from the submitted sample, the professional observations of numerous appointed dental practitioners, and product composition information obtained from manufacturer's material safety data sheets (MSDS). BioComp Labs may be limited by the amount of information released by each manufacturer. The information is supplied as a courtesy to health care providers to aid in an overall assessment of oral health. This information alone should not be used to diagnose and/or treat a health problem or disease. All reported results are intended for research purposes only and a consultation with a qualified health care provider is required.

OUTDATED AND FOREIGN MATERIALS

Some restorative medical materials listed in the BioComp Labs Compatibility Report are out of production and are no longer available. These materials are maintained in our database because there are still patients who have these materials in their mouths. Health care practitioners need to be able to determine whether the outdated materials are compatible with new materials. Some materials listed are unavailable in the United States, but are available in other countries. The health care practitioner should be aware of the biocompatibility of these materials as well.

PORCELAIN & CERAMIC CATEGORY

The materials in this category frequently contain aluminum oxide. Aluminum as a separate component nearly always registers in the highly reactive category (See Reactivity Summary, Page 1). Since all products are reported according to the highest level of reactivity among their components, nearly all of the porcelain and ceramic materials will therefore test as highly reactive. BioComp Labs believes that this a situation where the health care practitioner should use his/her professional judgement. Many dentists believe that any aluminum oxide sealed inside porcelain poses no significant challenge to the immune system. Other dentists believe that any source of aluminum is a significant challenge and should be avoided. It is up to the patient and the dentist to discuss options available. BioComp Labs has provided a 'Porcelain and Ceramics' product category as well as a 'Products (Various) - Omitting Aluminum Considerations' product category for your comparative convenience.

HOW TO BEST UTILIZE THE REPORTED INFORMATION

You will receive both an electronic (.pdf) copy and a hard copy bound report of your patient's serum biocompatibility findings. A table of contents separates materials into Product Categories (ex. composites, cements, etc.). Within each Product Category individual products are classified as Least, Moderately, and Highly Reactive based on the patient's serum compatibility results. Products may be listed in more than one Product Category, if applicable. Each product is followed by a five digit number (ex. 10159), which refers you to the last section of the report called Product Sources. This is a numerical list of the companies associated with each product. For example, 10159 is Microstar Corp., with company contact information listed. To best use this information the electronic file can be searched by either the product name and/or the product manufacturer.

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SECTION TWO - REACTIVITY LEVELS OF SPECIFIC DENTAL PRODUCTS

Note: The following results MUST be interpreted in view of the comments which comprise this Report's introduction. This specific blood serum analysis is NOT an universal endorsement or rejection of any single product. The test results apply ONLY to the specific patient tested.

REPORT FINDINGS

Cements

Products with one or more components which are LEAST REACTIVE

ACCOLADE PV (10153)	GLASSLINE (10069)	PHOSPHATE CEMENT (10108)
ACTIVA BIOACTIVE CEMENT (10069)	GLASSLUTE (10069)	POLYCARB WATERSET (10069)
ADHERENCE D/C (10105)	HELIOSIT ORTHODONTIC (10066)	POLY-F-PLUS (10090)
ADHERENCE S/C (10105)	HOFFMANNS CEMENT NS (10003)	PORCELITE DUAL CURE (10017)
ADHESE (10066)	HOFFMANNS CEMENT QS (10003)	POST CEMENT HI-X (10070)
ADHESE UNIVERSAL (10066)	HY-BOND POLYCARBOXY (10059)	PREPEZE DESENSITIZE (10067)
ADHESIVE BOND II (10108)	HY-BOND TEMP CEMENT (10059)	PRESERVE-PLUS (10036)
ADPER PROMPT (10014)	ILLUSION TRY-IN PAST (10070)	PREVISION CEM (10108)
ADPER SCOTCHBOND MP ADHESIVE (10014)	IONOFIL MOLAR (10158)	PROMPT L-POP (10014)
ADPER SCOTCHBOND MP PRIMER (10014)	IONOFIL MOLAR AC (10158)	PROTECT-IT (10067)
ANCHOR (10094)	IONOFIL MOLAR AC QUK (10158)	PROTEMP CROWN (10014)
APPEAL (10066)	IONOSEAL (10158)	PROVICOL SC SYSTEM (10158)
AQUACEM (10038)	IRM (10015)	PROVISACEM (10193)
AXCEL FLOW (10114)	KALSOGEN + SYSTEM (10038)	PROVISCCELL (10105)
BIFIX DC/QM (10158)	KALSOGEN PLUS POWER (10018)	RELYX ARC (10014)
BIO-CAP (10011)	KETAC BOND (10014)	RELYX ARC PASTE (10014)
BIOMER BASE PASTE (10015)	KETAC CEM + LUTING PASTE A (10014)	RELYX LUTING CEMENT (10014)
BISTITE II DC (10170)	KETAC CEM + LUTING PASTE B (10014)	RELYX LUTING PLUS (10014)
BOND-1 ACT/ADH (10067)	KETAC CEM MAXICAP LQ (10014)	RELYX TEMP E (10014)
BREEZE (10067)	KETAC FIL + APLICAP LIQUID (10014)	RELYX TEMP NE (10014)
BULK EZ (10153)	KETAC MOLAR QK SYSTEM (10014)	RELYX U100 (10014)
C&B CEMENT BASE/CATALYST (10070)	KETAC MOLAR SYSTEM (10014)	RELYX ULTIMATE SYSTEM (10014)
C&B METABOND SYSTEM (10032)	KETAC SILVER SYSTEM (10014)	RELYX VENEER CEMENT (10014)
CALIBRA CERAM (10015)	LICUPAST (10093)	RENAMEL CREATIVE COL (10096)
CALIBRA UNIV SELF-ADH RES (10015)	LIV CARBO SYSTEM (10028)	RESILUTE RESIN CEMNT (10069)
CARBICHEM AQUASET (10030)	LUTE-IT (10067)	RESIMENT (10105)
CARBOXYLATE CEMENT POWDER (10108)	MAXCEM (10017)	RESIMENT W/FLUORIDE (10105)
CEMENT-IT UNIV (10067)	M-BOND (10170)	RESINOMER (10070)
CERINATE PRIME (10011)	MERON AC (10158)	RESTODENT5 (10095)
CHOICE (10070)	MERON PLUS (AC) SYSTEM (10158)	RETAIN (10067)
CHOICE 2 (10070)	MERON SYSTEM (10158)	SCOTCHBOND DUAL CURE (10014)
CHOICE2 TRY-IN PASTE (10070)	MONOCHEM (10059)	SCOTCHBOND I XT (10014)
CIMARA ZIRCON (10158)	MULTILINK AUTOMIX SYSTEM (10066)	SEDANOL (10038)
CLEARFIL DC CEMENT (10169)	NEXUS (10017)	SENSITEMP NEZO (10161)
CLING 2 (10016)	NEXUS (10017)	SENSITEMP RESIN (10161)
COLORLOGIC (10080)	NEXUS 2 (10017)	SINGLE BOND ADHESIVE (10014)
COMPOSITE LUT CEMNT (10014)	NEXUS NX3 SYSTEM (10017)	SINTER BOND (10048)
CONCISE ORTHO BOND SYSTEM (10014)	NOBETEC SYSTEM (10062)	SUPERLON (10074)
CR INLAY CEMENT (10115)	NOGENOL TEMP CEMENT (10028)	SYSTEMP. LINK (10066)
DENTASTIC (10069)	NOMIX TEMPORARY CMNT (10009)	TEMP-BOND NE (10017)
DENTASTIC DUO (10069)	NX3 (10017)	TEMPOCEM (10160)
DETREY ZINC (10038)	ONE-STEP (10070)	TEMPOCEM NE (10160)
DIAMONDLINK (10151)	ONE-STEP PLUS (10070)	TEMPOCEM SOFT (10160)

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REPORT FINDINGS**Implant Materials****Products with one or more components which are LEAST REACTIVE**

ABUTMENT (10203)	HEALING ABUTMENT (10203)	SR VIVO TAC (10066)
AESTHETICA IMPLANTS (10199)	HEX CONIC (10195)	STANDARD IMPLANT (10202)
ANATOMIC ABUTMENT (10202)	HEX-OUT (10195)	STANDARD PLUS IMPLAN (10202)
ANGELED ABUTMENTS (10196)	LOCATOR ABUTMENT (10202)	TAPERED EFFECT IMPLA (10202)
ANGLED ABUTMENT (10203)	LOCATOR ABUTMENT (10203)	TEMPDESIGN (10203)
Ball Abt. Titanium Branemark (10168)	MESO ABUTMENT (10202)	TEMPORARY ABUTMENT (10203)
BALL ABUTMENT (10203)	MISTRAL (10198)	TI ABUTMENT FOR BARS (10202)
BALL ABUTMENT TITANIUM (10168)	MULTI-BASE ABUTMENT (10202)	TIDESIGN (10203)
BALL ABUTMENTS (10196)	NOBEL PROCERA (10168)	UNIABUTMENT (10203)
BRANEMARK SYSTEM (10168)	NOBELACTIVE (10168)	UNIVERSAL + (10199)
CARES CERAMIC ABUTME (10202)	NOBELPERFECT (10168)	UNO (10198)
CARES TITANIUM ABUTM (10202)	NOBELREPLACE (10168)	VITALLIUM SPECIAL (10018)
CASTDESIGN (10203)	NOBELSPEEDY (10168)	XIVE (10008)
CAST-TO ABUTMENT (10203)	OSSEOSPEED IMPLANTS (10203)	Z1 (10195)
CEMENTABLE ABUTMENT (10202)	PITT-EASY (10197)	Z1 CONIC (10195)
CONIC (10195)	PROFILE BIABUTMENT (10203)	Z1-CONNECT (10195)
CONNECT (10195)	PROVISIONAL IMPLANTS (10198)	ZIRABUTMENT (10203)
COVER SCREW (10203)	PURETEX (10197)	ZIRDESIGN (10203)
CROWN & BRIDGE ABUTM (10196)	SDS1.2 (10008)	ZIRKOLITH (10201)
CUSTOM PREPABLE ABUT (10196)	SEVEN (10198)	Z-LOCK 3 (10201)
DIRECT ABUTMENT (10203)	SR ORTHO TAC (10066)	Z-LOCK3 (10201)

Products with one or more components which are MODERATELY REACTIVE

There are no MODERATELY reactive products for this category.

Products with one or more components which are HIGHLY REACTIVE

ATLANTIS ABUT GOLD/TITAN (10035)	INTEGRA-CP (10200)	SNAPPY ABUTMENT (10168)
BICON TI IMPLANT (10200)	INTEGRA-TI (10200)	TAPERED IMPLANTS (10196)
CONICAL GROOVY IMPLA (10206)	INTERNAL (10196)	TAPERED INTERNAL (10196)
GOLD ABUTMENT/BARS (10202)	LOCATOR ABUTMENTS (10196)	THIN INTEGRAL IMPLAN (10206)
GOLD ABUTMENT/BRIDGE (10202)	ONE-PIECE 3.0 (10196)	THIN ONE STAGE IMPLA (10207)
GOLD ABUTMENT/CROWN (10202)	OVERDENTURE (10196)	THOMMEN ABUTMENTS (10233)
GOLDADAPT ABUTMENT (10168)	SCREW TYPE IMPLANT (10206)	THOMMEN IMPLANTS (10233)
GROOVY INTEGRAL (10206)	SINGLE-STAGE (10196)	TITANIUM BASE ALLOY (10221)
HEALING ABUTMENTS (10196)		

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Product Sources

Companies are listed to cross reference the individual products to the manufacturer of those respective products. The number following each product name corresponds to the manufacturer of the product as listed below.

10225	Reliance Orthodontic Products		
10002	Trubyte / Dentsply	800-786-0085	717-845-7511
10003	Hoffmann Dental Manufaktur	49 308510273	
10004	Adherer	800-542-5597	
10005	Bego	800-342-2346	508-643-0270
10006	Yates and Bird / Motloid Company	800-535-5053	352-353-3500
10007	Local Grocery / Drug Store Proc	Locally Avail	
10008	Dental Star	800-549-2207	
10009	Centrix Incorporated	800-235-5862	
10010	Coltene / Whaledent	800-221-3046	212-696-8000
10011	Den-Mat Corporation	800-433-6628	805-922-8491
10012	Pentron Laboratory / Zahn Dental	800-243-3100	
10014	3M Corporation	800-634-2249	
10015	Caulk / Dentsply	800-532-2855	302-422-4511
10016	Clinician's Choice	800-265-3444	519-641-3066
10017	Kerr Manufacturing Co.	800-537-7123	313-946-7800
10018	Austenal / Dentsply	800-621-0381	
10019	Johnson And Johnson	800-526-3967	201-524-0400
10020	Codesco, Inc.	800-549-5587	
10021	Talladium Inc.	800-221-6449	661-295-0900
10022	Neo Dental International Inc.	800-720-0096	253-946-0814
10023	Pascal Company, Inc.	800-426-8051	425-827-4694
10024	DiaDent Group International, Inc.	604-451-8851	
10025	Garreco Inc.	800-334-1443	501-362-6261
10026	Beutlich Pharmaceuticals	800-238-8542	847-473-1100
10027	Etkon USA	817-701-1181	
10028	GC America	800-323-7063	
10029	Sterngold	800-243-9942	508-226-5660
10030	PSP Dental Company Ltd.	02 083117337	
10031	Glaxo Smith Kline	866-844-2799	703-527-3887
10032	Parkell	800-243-7446	631-249-1134
10033	George Taub Products	800-828-2634	201-659-7186
10034	Astron Dental Corporation	800-323-4144	847-726-8787
10035	Dentsply	800-877-0020	800-487-0100
10036	Halex Products, Inc.	401-981-3223	
10037	DGS International	800-872-5483	
10038	Dentsply U.K.	44 1932853422	
10039	Java Crowns, Inc.	800-322-5282	281-583-9373
10040	Temrex Corporation	800-645-1226	516-868-6221